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## I. INTRODUCTION

Plaintiff, the International Brotherhood of Electrical Workers Local 38, Health and Welfare Fund (“IBEW”), seeks certification of three (3) sprawling and disparate classes of so-called Doryx “end-payers.” But it falls woefully short of the requirements of Rule 23—requirements that have become increasingly exacting in recent years in light of decisions from both the Supreme Court and the Third Circuit, including the Supreme Court’s decision just a few weeks ago in *Comcast v. Behrend*, 133 S. Ct. 1426 (2013). IBEW’s motion must be denied for at least the following reasons:

First, IBEW cannot carry its burden of demonstrating that it can show, through classwide proof, that each member of the proposed classes suffered injury (*i.e.*, impact) due to the claimed unlawful delay of generic Doryx capsules. Among other things:

- IBEW’s theory of impact depends on a series of completely unsupported—and unsupportable—assumptions about what the world would look like absent the complained-of conduct. For example, IBEW assumes that if generic Doryx capsules entered the market in 2006 (as Plaintiff claims they should have), Warner Chilcott would have abandoned its Doryx franchise, and not pursued any branded product extension. This assumption is contradicted by record evidence, including evidence that each product change was a material improvement, and Warner Chilcott *in fact* pursued a new branded Doryx product (its 200 mg tablet) after Mylan entered with generic forms of Doryx starting in 2011. If, as the evidence suggests, Warner Chilcott would have offered competing Doryx brands in the “but-for” world, IBEW cannot credibly assume that all class members would have purchased a generic capsule, as distinguished from a new branded Doryx product, in the but-for world.

- IBEW’s theory of impact likewise relies on the use of “averages” for important variables, including prices, generic penetration rates, co-pays and other cost-sharing levels, and other variables. When the variation masked by the averages is analyzed, however, it reveals a *lack* of common impact. And IBEW’s own economist conceded that at least two of the three subgroups within the proposed classes—uninsured consumers and insured consumers—have members that would not have been harmed by a delay in generic Doryx capsules. Patients falling into these categories are likely to number in the tens of thousands. IBEW has offered no way, short of individual inquiry, to identify such uninjured members of the proposed classes.

Second, IBEW’s proposal for calculating aggregate total damages is flawed for many of the reasons noted above, including its reliance on unsupported assumptions, its inability to properly account for consumers and/or third-party payers (“TPPs”) who would actually benefit from (or at least not be harmed by) a delay in generic entry, and its failure to account for the degree to which insurer class members passed any claimed overpayment on to premium payers, and others.

Third, IBEW offers no methodology for taking the lump-sum damage pool it proposes to calculate and assigning damages to individual class members. Plaintiff’s economist Rausser repeatedly asserted that all such uncertainties would be addressed in some undefined “claims administration” process at the end of the case. But mere promises to develop an adequate damages methodology in the future have never been acceptable, and most certainly are not after *Comcast*.

Fourth, the proposed classes fail because of the difficulty in ascertaining their members in the first instance. For example, the classes include TPPs who in fact were responsible (*i.e.*, “on

the risk”) for reimbursing Doryx prescriptions. But given the complex web of risk-sharing arrangements among insurers, pharmacy benefit managers, employers and other intermediaries, as well as the role of the federal and state governments in funding even “private” insurance (through, for example, Medicare Part D plans), it would be a complex and individualized task to identify which entities actually fit the class definition. IBEW has offered no methodology for doing so.

Fifth, the single proposed class representative, IBEW, a provider of pharmacy benefits to about 6,000 union members, is incapable of fairly and adequately representing the widely diverse members of the three classes proposed here. Each class includes (a) TPPs, such as health insurance companies, pharmacy benefit managers, self-insured employers, union health funds, health maintenance organizations and other entities providing pharmacy coverage; (b) consumers with pharmacy coverage requiring cost-sharing, such as co-pays, co-insurance and the like; and (c) uninsured cash-paying consumers. IBEW has virtually no stake in this litigation—even when generic Doryx entered, because IBEW’s members *stuck with the Doryx brand* and did not switch to generic Doryx. Nor has IBEW offered any explanation as to how it is capable of zealously protecting the interests of insured and uninsured *consumers*. At a bare minimum, there is an inherent conflict between benefit providers, such as IBEW, and their insureds, since any claimed overpayment associated with a reimbursed prescription must be divided between insurer and insured, with each side having an incentive to maximize its recovery at the expense of the other. Nor can IBEW’s claims be viewed as “typical” of those of cash paying consumers, on the one hand, or of nationwide insurance giants and self-funded employer groups, on the other.

Sixth, IBEW’s proposed national class for injunctive relief only must be rejected as an inferior mechanism for pursuing such relief. IBEW itself, together with multiple other plaintiffs,

already are pursuing injunctive relief against defendants, and the relief they seek is speculative and undefined. There is no need for a costly and time-consuming class action mechanism to obtain duplicative injunctive relief, and in any event, the IBEW's injunctive relief claims are too ill-defined to support standing. *See authorities cited in* Def. Mem. of Law in Support of the Mot. to Dismiss the Rite Aid Complaint, Dkt. No. 173 at 7 (*O'Shea* and *McCray*). Finally, the fact that the IBEW never had members who purchased generic Doryx makes them unsuited to represent any class of persons seeking the injunctive relief sought here.

Accordingly, IBEW's motion for class certification should be denied.

## **II. FACTUAL BACKGROUND**

### **A. The Markets in which Doryx Competes Are Crowded with Brand, Generic, and OTC Drug Alternatives and Are Highly Competitive**

Doryx—the branded form of delayed-release doxycycline hyclate—competes in a highly competitive and crowded marketplace with over 500 prescription and over-the-counter products available in the United States for the treatment of *acne vulgaris*. Warner Chilcott's Doryx competes in a marketplace with some of the largest and most sophisticated companies in the world, including Pfizer Inc. (\$59.0 billion in annual revenues)<sup>1</sup> and Novartis AG (\$56.7 billion in annual revenues).<sup>2</sup> Its share of the marketplace has consistently been small in the entire acne market, rarely exceeding 11% of the market segment for tetracyclines (comprised of doxycyclines, minocyclines, and other tetracyclines). Public sources and documents produced during discovery confirm that the competition is fierce and that multiple other pharmaceuticals are viewed as competitors of Doryx, both by competitors and by Warner Chilcott itself.

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<sup>1</sup> Pfizer Inc. 2012 Form 10-K Financial Report at 15 (Ex. 1).

<sup>2</sup> Novartis AG 2012 Form 20-F at 4 (Ex. 2). PharmaDerm, which markets and sells Adoxa (doxycycline monohydrate), is a division of Fougera Pharmaceuticals, Inc., which is an affiliate of Novartis AG. *Id.* at 75.

In the interest of avoiding undue duplication, Warner Chilcott incorporates by reference the more detailed background set forth in Warner Chilcott's Opposition to Direct Purchaser Plaintiffs' Motion for Class Certification ("DPP Opp. Br.").<sup>3</sup>

**B. Warner Chilcott Is a Relatively Small, Specialized Pharmaceutical Company Committed to the Doryx Franchise Even in the Face of Widespread Generic Competition for Acne Treatment**

Warner Chilcott is a modestly-sized specialty pharmaceutical company with a product portfolio consisting of nine principal products including Doryx, Warner Chilcott's flagship dermatology product.<sup>4</sup> [REDACTED]

[REDACTED]

[REDACTED]<sup>6</sup>

**C. Warner Chilcott's Strategy Was to Compete on Doryx through Product Improvements Even in the Face of Generic Competition**

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].<sup>7</sup> To gain a foothold in the competitive U.S. pharmaceutical market, it granted Warner Chilcott an exclusive license to market and sell Doryx in the United States in 1997.<sup>8</sup>

Warner Chilcott introduced a series of Doryx product extensions, each offering benefits over prior versions. *See* Webster Decl. ¶49. While the detail is found in the DPP Opposition

<sup>3</sup> If the Court would prefer a consolidated brief with full factual background, Warner Chilcott is happy to provide one.

<sup>4</sup> Warner Chilcott, PLC 2013 Form 10-K financial report, at 1 (Ex. 3).

<sup>5</sup> [REDACTED] (Ex. 4).

<sup>6</sup> [REDACTED]

<sup>7</sup> [REDACTED]

<sup>8</sup> *Id.* at ¶ 8. Mayne continues to manufacture Doryx for Warner Chilcott to sell in the United States.

Brief, we summarize the dates of entries and principal advantages of the Doryx product introductions below:

- ***75 mg Doryx capsules provided dosing flexibility.*** After receiving FDA approval in August 2001, Defendants launched a 75 mg Doryx capsule in the United States in January 2002. The 75 mg capsule provided patients and physicians with a more flexible, lower-dose doxycycline option.<sup>9</sup>
- ***Doryx tablets addressed safety, stability, and competitive concerns, and provided a patent-protected platform for future improvements (scoring).*** FDA approved Doryx tablets in May 2005, and Warner Chilcott launched the new Doryx product in August 2005. The Doryx tablet provided physicians and patients with a safer, more stable delayed-release product. Specifically, the tablet versions of Doryx (1) decreased the risk of esophageal irritation and/or ulceration and achieved a shelf-life of 24 months (versus 12 months for the capsule); (2) responded to competition (competitors were highlighting esophageal sticking/ulceration and swallowing issues in negative marketing against Doryx capsules); and (3) allowed the use of patent-protected technology in a dosage form that would allow for scoring in the future, thus providing greater dosing flexibility.<sup>10</sup>
- ***Applesauce labeling benefits for patients.*** Warner Chilcott responded to physician feedback and, based on patient studies, obtained FDA-approved labeling changes in June 2003 (capsules) and December 2006 (tablets). Applesauce labeling increased flexibility in dosing, provided an easier method of administration for patients who had difficulty swallowing pills, and provided a widely accessible and easily administrable doxycycline product that could be given in the event of an anthrax emergency.<sup>11</sup>
- ***Scoring provided additional flexibility and matched competition.*** Warner Chilcott launched the 75, 100, and 150 mg tablets in March 2009, February 2009, and July 2008, respectively, shortly after receiving FDA approval. These scored tablets provided myriad benefits, including: increased flexibility in dosing for physicians, increased ease of swallowing, lower copays, accuracy and equivalence in drug distribution in splitting tablets, and increased marketing strength (competitors were marketing scored tablets and meeting physician needs for the flexibility to customize dosing by a patient's weight). The dual-scored 150 mg Doryx product (FDA approved in September 2011) provided all of the benefits referred to above more conveniently in just one pill.<sup>12</sup>

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<sup>9</sup> DPP Opp. Br. at C.1.

<sup>10</sup> See DPP Opp. Br. at C.2; see also Webster Decl. ¶¶ 83, 87.

<sup>11</sup> See DPP Opp. Br. at C.3; see also Webster Decl. ¶¶ 90–92.

<sup>12</sup> See DPP Opp. Br. at C.4; see also Webster Decl. ¶¶ 98–109.

- ***New indication for 200 mg Doryx.*** Just last month, Defendants received FDA approval of a 200 mg Doryx tablet. In addition to the indications for acne and other conditions provided on the prior Doryx label, the 200 mg tablet provides additional benefits of a newly approved treatment regime for chlamydia, a 200 mg single tablet Doryx dosing option, and increased flexibility in dosing.<sup>13</sup>

**D. IBEW’s claim: That Introduction of New Products can be Unlawful if Not Enough of an Improvement over Prior Versions**

IBEW claims that Warner Chilcott’s introductions of the reformulated versions of Doryx were anticompetitive. IBEW asserts that the reformulated versions “offer[ed] no medical or clinical benefits over the prior formulations of Doryx.” IBEW Opp. to Warner Chilcott’s Motion to Dismiss Indirect Purchaser, Dkt. No. 113 (Nov. 15, 2012), at 30 (“IBEW MTD Opp.”). While it concedes (as it must) that the mere introduction of new products alone is not anticompetitive, IBEW claims that the new product introductions somehow were rendered anticompetitive here when “combined with the withdrawal of the prior formulations of Doryx.” *Id.*

As the Court knows, Warner Chilcott vigorously denies that the introduction of a new product, even combined with the withdrawal of the old, can be viewed as anticompetitive. Warner Chilcott Mot. to Dismiss IBEW Compl., Dkt. No. 101, dated Oct. 31, 2012, at 15–16; Warner Chilcott Mot. to Dismiss Mylan Compl., Dkt. No. 84, dated Oct. 1, 2012, at 12–15. Indeed, the discontinuance of older versions of products when newer ones are introduced is commonplace—Toyota stops selling and promoting 2012 Camrys when the new 2013 models arrive (even if the 2013 model is pretty much the same as the 2012). Even under IBEW’s theory, however, the introduction of a product that in fact provides “medical or clinical benefits over prior [versions]” should not be anticompetitive. IBEW MTD Opp. at 30.

IBEW claims that as a result of Warner Chilcott’s product introductions (and withdrawals) the entry of generic versions of Doryx capsules was impaired. According to

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<sup>13</sup> See DPP Opp. Br. at 5; see also Webster Decl. ¶ 110.

IBEW, absent Warner Chilcott's "wrongdoing," generic Doryx capsules would have entered in substantial quantities in July 2006.<sup>14</sup>

**E. Plaintiff's Three Proposed End-Payer Classes—Each Is Diverse and Includes Differently-Situated Members**

IBEW proposes to serve as the representative for three classes, two state law classes under Rule 23(b)(3) and one federal, injunction-only, class under Rule 23(b)(2). The proposed Florida indirect purchaser class is defined to include persons or entities "who reimbursed for, or indirectly purchased, other than for resale, branded Doryx in the state of Florida, from any of the Defendants, other than for resale," from 2008 forward, and excludes Defendants and related entities and individuals, as well as "fully-insured health plans, i.e. plans that purchased insurance from another third party payer covering 100% of the Plan's reimbursement obligations to its members, and all governmental entities." Mem. of Law in Support of Indirect Purchaser Plaintiff's Mot. for Class Cert., Dkt. No. 150 (Apr. 1, 2013), at 2 ("IBEW Class Cert. Brief"). The proposed Nevada indirect purchaser class uses the same definition, substituting "Nevada" for "Florida" as the relevant location. *Id.* The proposed federal injunction class seeks to encompass "[a]ll persons or entities in the United States and its territories who reimbursed for, or indirectly purchased, other than for resale, branded Doryx from any of the Defendants," during the same time period and subject to the same exclusions as the two state law classes. *Id.*

IBEW is a union health and welfare trust fund that provides a pharmacy benefit to approximately 6,000 members. IBEW is based in Ohio and has few members residing in Florida or Nevada. [REDACTED]

[REDACTED].<sup>15</sup> Moreover, although this case is about the

<sup>14</sup> [REDACTED] (Ex. 5).

<sup>15</sup> [REDACTED] (Ex. 6).

supposed denial of an opportunity to purchase generic Doryx sooner, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]<sup>16</sup>

Nonetheless, IBEW proposes to represent the above-noted three classes. Each is widely diverse, consisting of at least three categories of members:

### **1. Uninsured Consumers**

Uninsured consumers are those who lack pharmacy benefits and therefore pay cash for their pharmaceuticals. The pricing of both brand and generic drugs to such cash payers depends on the prices set by the respective manufacturers, as well as the markups imposed by middlemen in the pharmacy distribution chain. In the case of branded drugs, the manufacturer ships to wholesalers, who in turn ship to retail pharmacies (as well as clinics, hospitals and other healthcare facilities).<sup>17</sup> In the case of generic drugs, manufacturers not only ship to wholesalers but also sell directly to various large retail pharmacy chains, mass merchandisers and supermarket chains. *See, e.g., Valley Drug Co. v. Geneva Pharms., Inc.*, 350 F.3d 1181 (11th Cir. 2003) (noting by-pass phenomenon).

As IBEW's own economist, Dr. Gordon Rausser, has conceded (in opposing certification in a recent case involving the same kind of end-payer class action at issue here), pricing and markups at each level of those distribution chains varies considerably. To take just the markups by retail pharmacists, Dr. Rausser explained: "Pharmacies' markups to cash-paying customers . . . vary considerably, depending, for example, on the pharmacy's location and business strategy."

<sup>16</sup> [REDACTED]

<sup>17</sup> Kaiser Report, *Follow the Pill: Understanding U.S. Commercial Pharmaceutical Supply Chain*, at 8 (Ex. 10).

Some pharmacies are located in mass merchandising stores, which use low drug prices to increase the foot traffic in their stores as a way to sell other products. . . . [O]ther pharmacies, such as those in rural areas, have little competition and can mark up their drug prices considerably.” Redacted Declaration of Gordon Rausser, Ph.D., in support of Defs. Opp. to Pls.’ Mot. for Class Cert., *Weiss v. AstraZeneca*, Dkt. No. BC323107 (Cal. Sup. 2008), ¶ 113 (emphasis added) (“Rausser Nexium Decl.”) (Ex. 11). Retail pharmacists are also known to take more substantial markups on generic drugs than they do for branded ones. According to Dr. Rausser, “Because the cash register price paid by uninsured consumers varies significantly from pharmacy to pharmacy, the use of an ‘average’ retail price obscures important differences among class members’ purchases.”<sup>18</sup> *Id.* ¶ 55. As discussed below, in this case Dr. Rausser relies upon just such averages.

Adding to the diversity in pricing are discounts, coupons and free samples that were offered by Warner Chilcott on branded Doryx, but which would not have been offered by a generic. [REDACTED]

[REDACTED]

[REDACTED]<sup>19</sup> [REDACTED]

[REDACTED]

[REDACTED] Again, in the words of IBEW’s economist: “Because generic drug manufacturers seldom offer incentives of this type, any analysis that fails to factor

<sup>18</sup> A 2004 study by the New York City Council found vast differences in the prices charged at retail within a single neighborhood. See “Prescription Drug Prices: All Over the Map” Staff Report to the Committee on Oversight and Investigations, February 2004, at 2 (Ex. 12). In just the borough of Manhattan, the study found cash prices for Prevacid varied by as much as \$78.05 per prescription. *Id.* at 17. Prices for the allergy medication Allegra varied from a low of \$61.95 to a high of \$106, a difference of over 70%. *Id.* For the arthritis drug Celebrex, the study found that pharmacy prices in New York City varied from \$60.16 to \$128.00 for the same quantity and strength – a difference of over 100%. *Id.*

<sup>19</sup> [REDACTED] (Ex. 13),

in the effect of consumer coupons and rebates will provide a deceptive picture of the relative costs of [brand] and [generic].” Rausser Nexium Decl. ¶ 39.

For example, assume the retail price for a one month supply of a branded pharmaceutical was \$100 and a particular consumer needed a three month supply. If the patient received free samples covering the first month and then used coupons worth, say, \$30 each for the next two months, the patient’s effective cost for the three month supply would be \$140 (\$0 (first month)) + (\$100 - \$30 (second month)) + (\$100 - \$30) (third month)). If the generic price was \$50 per month (half the retail price of the brand), that patient’s effective cost for three months of the generic would be \$150—\$10 more than for the brand when coupons and sampling are factored in. Such a consumer would not be harmed by a delay in the availability of the generic. As discussed below, Dr. Rausser made no such assessment in this case.

## 2. Consumers with Insurance

Consumers with prescription drug coverage often pay the pharmacy only a co-payment or deductible for covered prescriptions. Their coverage provider pays the rest under an agreement between the provider (or its pharmacy benefits manager) and the pharmacy. Expert Decl. of Gordon Rausser ¶ 100. The types of cost-sharing mechanisms vary not only between and within coverage providers, but also over time. Kaiser Family Foundation Annual Survey 2012 (“Kaiser 2012”) at 149–50, 153.

For example, some plans have so-called flat co-pays, in which the co-pay for the brand and the generic are the same. [REDACTED]

[REDACTED]; see Kaiser Annual Surveys 2006 through 2012 (reference to all six surveys, “Kaiser Surveys”) (showing that about 1 to 2% of covered patients nationally had flat co-pay plans

between 2006 and 2012, implying thousands of patients) (Exs. 14–20). Other plans have deductibles, in which the patient is responsible for all pharmacy expenditures up to a dollar limit, and thereafter the plan covers all prescription expenditures, whether brand or generic. *See* Kaiser 2012 at 148 (19% of covered patients nationally enrolled in high deductible plans have 100% of prescription costs once plan deductible is met), at 150 (5% covered by plans in which there is no cost sharing after deductible is met). If a patient needs Doryx for the first time after she has exceeded the deductible, and there is no cost sharing after the deductible has been met then she would not be impacted by a delay in generic availability. Here, the question of impact will depend on the timing of the prescription in relation to other health care expenditures, as well as the deductible limit of the particular plan, a highly individualized inquiry.

Other plans have differential co-pays, in which the co-pay for a generic drug is lower than that for a branded pharmaceutical. The number of co-pay tiers and the spreads between tiers vary widely plan to plan. Kaiser 2012 at 148–49; [REDACTED] (Ex. 21) [REDACTED]. And even where a differential co-pay is in place, the question whether an individual consumer is impacted by a delay in generic entry will depend on the sampling and coupon issues discussed above (in the context of uninsured consumers). For example, if the co-pay for a branded prescription under a particular plan is \$40, and the patient receives a free one-month sample and utilizes a coupon that defrays the co-pay by \$25, the net out-of-pocket cost for a three month supply of the brand would be \$30 (\$0 (month one, free sample)) + (\$40 - \$25) (month two) + (\$40 - \$25) (month three)). If the co-pay for the generic is \$10 per prescription, the net cost to the patient for a three month supply is \$30—the same as for the brand. Such a patient would not be impacted by a delay in generic entry.

The types of plans offered run the gamut of terms. Indeed, major insurers such as United Health Care or Blue Cross/Blue Shield themselves offer myriad different plans to their millions of insured patients. *See* United Health Group 2013 Form 10-K, at 2.

Dr. Rausser has conceded that assessing any individual patient's experience is an individualized undertaking. For example, "a covered consumer's co-pay is not predictable. One must have specific information about the consumer's particular prescription drug plan and the date when the purchase was made in order to know the co-pay applicable to the target drug purchase and/or to the purchase of a hypothesized alternative therapy on that same day."<sup>20</sup> Dr. Rausser also acknowledged that changing coverage status is important and is difficult to track in any formulaic manner: "[E]ven fundamental characteristics (such as whether an individual is insured or uninsured) will change over time (as he or she is employed or unemployed) in ways which cannot be tracked."<sup>21</sup> As discussed below, no such individualized consideration is found in Dr. Rausser's analysis in this case.

### **3. Third Party Payers (TPPs)**

A TPP pays what remains of the amount owed to the pharmacy after deducting the co-pay provided by the consumer. A TPP may pay the full amount where, for example, the plan's deductible has been exceeded. The amount a TPP will pay for branded and generic prescriptions is negotiated between the TPP and the pharmacy. As Dr. Rausser admitted, such negotiated reimbursement rates "*vary considerably* according to pharmacy and [TPP]" and depend on such things as the number of covered patients the TPP controls, the number of pharmacies competing in the geographic area and other factors. *Id.* ¶ 123.

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<sup>20</sup> Rausser Nexium Decl. ¶ 42.

<sup>21</sup> Rausser Nexium Decl. ¶ 160.

In order to assess a TPP's net cost to reimburse for a particular drug, one must also consider rebates that the TPP may receive, directly or indirectly, from the drug's manufacturer. *See* Rausser Nexium Decl. ¶ 44 (“To calculate the *actual* cost to the third party payer, the third party payment [to the pharmacy] must be adjusted for manufacturer's rebates.”). Dr. Rausser explained: “[M]anufacturers of branded pharmaceuticals often enter into agreements with [TPPs] under which the manufacturer agrees to pay them a rebate if the drug is placed on their formulary, given a favorable formulary position, and/or reaches certain sales levels.” *Id.* ¶ 44. Dr. Rausser also admitted that manufacturer rebates are “*highly variable* . . . [O]ne would expect significant variability in the rebates a single manufacturer pays to different third party payers.” *Id.* ¶ 129.

In commenting on the complexities across all the types of members of an end-payer class such as this one, Dr. Rausser stated as follows:

The cost of a particular [drug] therapy depends upon a host of factors specific to the individual consumer or third party payer members of the proposed class. Among these factors are the pharmacy where the drug was purchased; the prescription drug plan providing insurance coverage and its specific benefit design; the daily dose taken; the duration of use; the number and amount(s) of coupons redeemed by the consumer; the number of free samples received by the consumer; the number and amount(s) of manufacturer rebates received by the third party payer or its PBM; . . . the contractual relationship between the third party payer and its PBM; and the time period over which the drug was purchased. Each of these individual factors is highly variable across proposed class members.

*Id.* ¶ 98. Again, as discussed below, Dr. Rausser's declaration in this case contains no such discussion.<sup>22</sup>

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<sup>22</sup> Plaintiffs cannot claim that Dr. Rausser's opinions in *Nexium* are inapplicable here because (i) his *Nexium* opinions addressed marketplace facts, such as the pricing and risk-sharing complexities associated with pharmaceutical distribution, that do not vary depending on the product, and (ii) the *Nexium* litigation concerned analogous allegations—claims that end payers purchased a product that was supposed to be an improvement but supposedly was not and that in the but-for world end payers would have purchased a different, cheaper product than the one actually purchased. Moreover, as discussed below, Dr. Rausser's rendition of the various ways in which

**F. Dr. Rausser’s Proposed Methodology to Assess Impact and Damages Impermissibly Depends on Assumptions, Averages and Generalizations**

IBEW depends entirely on Dr. Rausser to establish that classwide impact and damages can be proven using common evidence. To conclude that all members of the proposed classes would have been impacted by delayed generic entry, Dr. Rausser relies on top-line averages and generalizations; he does not discuss the complexities and individual issues that he took great pains to enumerate in his analysis discussed above.

Instead, Dr. Rausser uses the following “logic” to arrive at his conclusion:

- Without actually analyzing the medical or other benefits of Warner Chilcott’s follow-on Doryx products, Dr. Rausser asserts that they represented “immaterial” improvements; then assumes that, in the but-for world in which generic capsules would have entered in 2006, Warner Chilcott would have abandoned any further improvements – leaving the world limited to Doryx 75 and 100 mg capsules and generic equivalents. Rausser Decl. ¶¶ 17, 37, 121.
- Without analyzing the wherewithal or interest of any generic firm to do so, Dr. Rausser assumes that in the but-for world “at least half a dozen” generic firms would introduce generic forms of Doryx capsules in July 2006. *Id.* ¶¶ 21, 122
- Having assumed away any Doryx improvements that might have competed against his assumed generic capsule entrants, Dr. Rausser then purports to develop a classwide average “overcharge” by comparing the average actual prices for branded Doryx tablets with but-for prices of hypothetical generic capsules, ignoring that these products are not equivalent (*i.e.*, they are not AB-rated). *Id.* ¶¶ 118, 122.
- He then adopts an average generic penetration rate which he bases on academic literature addressing products having nothing to do with Doryx or acne medications. *Id.* ¶ 124.
- He applies the average penetration rate to the total sales of Doryx during the class period—providing, in his view, a universe of affected sales, *i.e.*, sales that he claims would have been generic in the but-for world. *Id.* ¶ 123.
- He then applies his average “overcharge” to his affected sales total to arrive at a total pot of “overcharge” damages. *Id.* ¶ 128.

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consumers could not be impacted by using a more expensive drug (*e.g.*, flat co-pay plans, brand loyalists, use of coupons) apply as fully here as they did in Nexium. Needless to say, Dr. Rausser’s attention to such issues in Nexium, and his silence on the same issues here, is striking.

Among other things, Dr. Rausser makes no effort to assess the kinds of individualized “no-impact” scenarios discussed above for both insured and uninsured consumers, the degree to which the combination of manufacturer rebates, co-pays and sampling would impact the net prices paid by individual TPPs,<sup>23</sup> or the degree to which the TPPs passed on any assumed cost increases in the premiums they charge. And although he concedes that certain adjustments must be made (*e.g.*, for manufacturer rebates, consumer coupons and samples), the types of adjustments he describes are aggregate in nature and thus cannot reveal the individualized “no-impact” situations that are at the heart of a predominance analysis. *See, e.g.*, Cremieux Decl. ¶¶ 17–20.

Moreover, Dr. Rausser offers no methodology, formulaic or otherwise, for assessing how to divide any aggregate damages figure he calculates among the members of the putative classes.<sup>24</sup>

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<sup>23</sup> [REDACTED]

<sup>24</sup> IPP Mot. at 32–33; Rausser Decl. ¶¶ 119–20, 123–24, 126–27; Cremieux Decl. ¶ 21, 103–14. Dr. Rausser also references the filing of citizen petitions, Rausser Decl. ¶ 37, but he offers no basis to suggest that any Warner Chilcott citizen petition delayed FDA approval of any generic Doryx product, let alone the generic capsules upon which his but-for world depends. Nor does IBEW argue that any Warner Chilcott citizen petition was a sham. *See, e.g.*, IBEW Opp. to Motion to Dismiss, at 27 (“Plaintiff does not challenge Defendants’ September 2011 Citizen Petition, nor its NDAs, as ‘sham petitions.’”).

Dr. Rausser also offers opinions on such merits issues as whether Warner Chilcott possesses monopoly power or can be viewed to have anticompetitive intent. Rausser Decl. ¶¶ 34–36. While we disagree with his conclusions, we do not address them at this class certification stage. They will be refuted at the appropriate juncture during the merits phase of expert discovery.

### III. ARGUMENT

#### A. The Standard for Certifying Classes Has Become more Exacting, Particularly in light of the Supreme Court's Recent Decision in *Comcast v. Behrend*, which Reinforced the Demanding Requirements of Rule 23, Including Consideration of the Merits of the Case

##### 1. IBEW Has the Burden of Showing that the Proposed Classes Satisfy Each of the Requirements of Rule 23

Class actions are “an exception to the usual rule that litigation [be] conducted by and on behalf of the individual named parties only.” *Comcast Corp. v. Behrend*, 133 S. Ct. 1426, 1432 (2013) (quoting *Califano v. Yamasaki*, 442 U.S. 682, 700–701 (1979)). Rule 23 sets forth IBEW’s burden when seeking to certify a class action.<sup>25</sup> For each of the three proposed classes, IBEW must satisfy the adequacy, typicality, numerosity, and commonality criteria of Rule 23(a). In addition, IBEW must satisfy the predominance and superiority requirements under Rule 23(b)(3) for the Nevada and Florida classes, which requires that “the court find[] that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.” Fed. R. Civ. P. 23(b)(3). “If proof of the essential elements of the cause of action requires individual treatment, then class certification is unsuitable.” *In re Hydrogen Peroxide*, 552 F.3d 305, 311 (3d Cir. 2008) (quoting *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 172 (3d Cir. 2001)). For the injunction class, IBEW must satisfy Rule 23(b)(2), which requires proof that Defendants have “acted or refused to act on grounds that apply generally to the class, so that final injunctive relief

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<sup>25</sup> IBEW has brought both federal and state law claims. However, since it proceeds in federal court, class certification as to all of the claims is evaluated under Rule 23 of the Federal Rules of Civil Procedure. *See, e.g., Shady Grove Orthopedic Assoc. v. Allstate Ins.*, 130 S. Ct. 1431, 1447–48 (2010) (holding that all claims in putative class action are subject to Rule 23 as “a Federal Rule governing procedure is valid whether or not it alters the outcome of the case in a way that induces forum shopping”).

or corresponding declaratory relief is appropriate respecting the class as a whole.” *McNair v. Synapse Group, Inc.*, 2010 WL 4777483, at \*3 (D.N.J. Nov. 15, 2010).

## **2. This Court Must Resolve Merits Disputes if Needed to Assess Rule 23 Requirements**

Trial courts are now required to rigorously evaluate whether plaintiffs have satisfied each and every requirement of Rule 23, through evidentiary proof, even if that means reaching “merits” issues. *See Hydrogen Peroxide*, 552 F.3d at 317 (“Because the decision whether to certify a class requires a thorough examination of the factual and legal allegations, the court’s rigorous analysis may include a preliminary inquiry on the merits.”) (internal citations omitted); *see also id.* (“Other courts of appeals have agreed [that a merits inquiry is only precluded if it is not necessary to determine a Rule 23 requirement].”); *In re New Motor Vehicles Can. Exp. Antitrust Litig.*, 522 F.3d 6, 24 (1st Cir. 2008) (“[I]nquiry into the merits at the class certification stage is not only permissible but appropriate to the extent that the merits overlap the Rule 23 criteria.”). This “rigorous analysis” is important because an overly permissive certification of classes can violate the Rules Enabling Act, which bars procedural rules from abridging, enlarging, or modifying any substantive rights. 28 U.S.C. § 2072(b); *Wal-mart Stores Inc. v. Dukes*, 131 S. Ct. 2541, 2561 (2011); *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 613 (1997); *Hohider v. United Parcel Serv., Inc.*, 574 F.3d 169, 185 (3d Cir. 2009). For example, in an antitrust case, the Third Circuit has held, “individual injury (also known as antitrust impact) is an element of the cause of action; to prevail on the merits, every class member must prove at least some antitrust impact resulting from the alleged violation.” *Hydrogen Peroxide*, 552 F.3d at 311. If a court certified a class and then proceeded to trial with a class methodology that assumes, but cannot actually establish, that all class members were impacted by the challenged conduct, the defendants’ substantive rights would have been abridged in violation of the Rules

Enabling Act. Likewise, such analysis minimizes the unfairness concerns inherent in permitting class actions, whereby the mere certification of a nationwide class can place “‘insurmountable pressure’ on a defendant to settle, even where the defendant has a good chance of succeeding on the merits.” *Regents of U. of Cal. v. Credit Suisse First Bos., Inc.*, 482 F.3d 372, 379 (5th Cir. 2007) (citation omitted); *see Hydrogen Peroxide*, 552 F.3d at 310 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007)) (“Certain antitrust class actions may present prime opportunities for plaintiffs to exert pressure upon defendants to settle weak claims.”).

The *Comcast* Court reiterated the district courts’ obligation to carefully scrutinize class certification motions. In *Comcast*, the Supreme Court reversed a decision of the Third Circuit, and made clear that district courts can no longer wait until the “merits” stage to address issues that bear on the requirements of Rule 23—including the requirement of Rule 23(b)(3) that common issues predominate in terms of both antitrust injury and damages. As the Court made clear, “[I]f anything, Rule (b)(3)’s predominance criterion is even more demanding than Rule 23(a). . . . Rule 23(b)(3), as an ‘adventuresome innovation,’ is designed for situations ‘in which class-action treatment is not as clearly called for’ . . . . That explains Congress’s addition of procedural safeguards for (b)(3) class members beyond those provided for (b)(1) or (b)(2) class members (e.g., an opportunity to opt out and receive notice), and the court’s duty to take a ‘close look’ at whether common questions predominate over individual ones.” 133 S. Ct. at 1432.<sup>26</sup>

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<sup>26</sup> Since *Comcast*, courts and commentators have noted that the Supreme Court’s decision has made the requirements for class certification more exacting. *See, e.g., Phillips v. Asset Acceptance, LLC*, 2013 WL 1568092, at \*3 (N.D. Ill. Apr. 12, 2013) (acknowledging that certain prior class certifications may not survive recent decisions, such as *Comcast*, which “may portend a tightening of class certification standards”); *Roach v. T.L. Cannon Corp.*, 2013 WL 1316452, at \*3 (N.D.N.Y. Mar. 29, 2013) (denying class certification in light of *Comcast*); *Martins v. 3PD, Inc.*, 2013 WL 1320454, at \*8, n. 3 (D. Mass. Mar. 28, 2013) (noting that in *Comcast*, the Supreme Court “has called . . . into question” the proposition that “courts generally find the predominance requirement satisfied even if individual damages issues remain”).

The “close look” mandated by *Comcast* will “frequently entail ‘overlap with the merits of the plaintiff’s underlying claim.’” *Id.* Reaching the merits includes resolving disputes among conflicting expert testimony and/or resolving the admissibility of proffered expert testimony. *See, e.g., West v. Prudential Sec., Inc.*, 282 F.3d 935, 938 (7th Cir. 2002) (observing that a “district judge may not duck hard questions by observing that each side has some support, or that considerations relevant to class certification may also affect the decision on the merits,” and finding that where “the judge . . . thought the clash [of experts] enough by itself to support class certification and a trial on the merits,” that “amounts to a delegation of judicial power to the plaintiffs, who can obtain class certification just by hiring a competent expert”); *In re Methionine Antitrust Litig.*, 204 F.R.D. 161, 165 (N.D. Cal. 2001) (evaluating expert’s opinion and concluding that “[the expert’s] method will not determine whether an individual class member has in fact been injured by the price-fixing conspiracy”); *In re Agric. Chems. Antitrust Litig.*, 1995 WL 787538, at \*5–7 (N.D. Fla. Oct. 23, 1995) (finding that impact could not be shown on classwide basis because, inter alia, Plaintiffs’ expert essentially assumed classwide impact and data contradicted his conclusions); *Dry Cleaning & Laundry Inst. of Detroit, Inc. v. Flom’s Corp.*, 1993 WL 527928, at \*5-6 (E.D. Mich. Oct. 19, 1993) (finding that plaintiff’s expert had “not conducted a thorough empirical analysis of the market and fare structures involved . . .”).

Evaluation of an expert’s conclusions plainly is part of the “rigorous analysis” that Rule 23 requires. District courts are not obligated to accept as true any assertion that a testifying expert is willing to make without regard to the facts.

#### **B. Courts Refuse to Certify Proposed Indirect Purchaser Classes due to Complexities that make Certification Improper**

Even prior to *Comcast*, courts have been suspect of indirect purchaser class actions in the pharmaceutical industry because its distribution and reimbursement complexities create a host of

individualized issues regarding impact and damages. Indirect purchaser classes like the ones proposed here have been consistently rejected. For example, in *K-Dur*, where a proposed class of end-payer plaintiffs alleged that a patent settlement agreement unlawfully delayed entry of a generic product, the district rejected the class, finding that plaintiffs did not satisfy the predominance requirement. Special Master’s Report and Recommendation on the Indirect Purchaser Plaintiffs’ Amended Motion for Class Certification, at 26, *In re K-Dur Antitrust Litig.*, No. 01-1652 (JAG) (Consolidated Cases), MDL Docket No. 1419 (D.N.J. Mar. 27, 2008). The court explained that (1) some TPPs paid more for the generic than the brand because the reduction in price of the generic did not offset the lower co-pay received by the TPP for the generic, and (2) consumers with “no co-pay or a flat co-pay” paid the same amount out-of-pocket regardless of whether they purchased the brand or the generic. These “variable co-pays structures” meant that significant numbers of TPPs and consumers “presumably” suffered no injury. *Id.* at 22. As shown below, all these issues are present here.

Similarly, in *Sheet Metal Workers*, a proposed class of end payer plaintiffs alleged that defendants filed sham patent infringement litigation aiming to prevent generic manufacturers from entering the market for generic Wellbutrin SR. *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 2010 WL 3855552, at \*2 (E.D. Pa. Sept. 30, 2010). The court rejected the proposed class. *Id.* at \*31. Based on the complex web of co-pay structures and variations among these structures, the court found that several categories of consumers—consumers who first purchased Wellbutrin in a generic form and did not pay co-insurance; consumers who paid the same co-payment for both generic and branded drugs; and brand loyalists—suffered no impact and could not be identified and excluded from the class in a

formulaic manner. *Id.* at \*26, 30 (citing *Reed v. Advocate Health Care*, 268 F.R.D. 573 (N.D. Ill. 2009)).<sup>27</sup>

A few courts, applying pre-*Comcast* standards for assessing common impact, partially certified classes where, unlike here, it was possible to identify clearly non-impacted class members—usually because the generic in question had already entered and real-world impact assessments were possible. Such class members could then be excluded. *See Wellbutrin XL*, 282 F.R.D. 126, 131, 145 (E.D. Pa. 2011) (excluding consumers with flat co-pays and brand-loyal patients where generic entry had actually occurred and data was available); *In re Flonase Antitrust Litig.*, 284 F.R.D. 207, 216 (E.D. Pa. 2012) (excluding flat co-pay patients where real-world entry data available); *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 326 (E.D. Mich. 2001) (excluding persons who did not purchase the generic form and flat co-payers where real-world entry data was available); *In re Terazosin Hydrochloride Antitrust Litig.*, 220 F.R.D. 672 (S.D. Fla. 2004) (excluding brand loyalists where real-world entry data available); *In re Relafen Antitrust Litig.*, 221 F.R.D. 260 (D. Mass. 2004) (excluding those who paid the same for brand and generic, based on real-world data). Here, since IBEW focuses on a generic that has not entered (generic Doryx capsules), no real-world data is available.

Thus, there is no easy “fix” to the no-impact issue here and the proposed classes must be rejected in their entirety.

### **C. Individual Issues Predominate on the Question of Impact**

The Third Circuit has warned that, at the class certification stage, “impact often is critically important for purposes of evaluating Rule 23(b)(3)’s predominance requirement

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<sup>27</sup> See also, e.g., *A&M Supply Co. v. Microsoft Corp.*, 654 N.W.2d 572 (Mich. 2002) (denying certification of indirect purchasers of Microsoft products under Michigan law); *Ludke v. Philip Morris Cos.*, 2001 WL 1673791 (D. Minn. Nov. 21, 2001) (denying certification of indirect purchasers under Minnesota law); *Kerr v. Abbott Labs*, 1997 WL 314419 (D. Minn. Feb. 19, 1997) (same); *In re Brand Name Prescription Drugs Antitrust Litig.*, 1994 WL 663590 (N.D. Ill. Nov 18, 1994) (denying certification of indirect purchaser class under Alabama law).

because it is an element of the claim that may call for individual, as opposed to common, proof.” *Hydrogen Peroxide*, 552 F.3d at 311; *see also, e.g., Ala. v. Blue Bird Body Co.*, 573 F.2d 309, 327 (5th Cir. 1978) (“‘[I]mpact’ is a question unique to each particular plaintiff and one that must be proved with certainty;” common evidence must allow “each plaintiff [in the proposed class] . . . [to] prove that this conspiracy . . . did in fact cause him injury.”). Thus, even if antitrust wrongdoing can be shown with common proof, *every* class member, representative and absent, must prove impact. *In re OSB Antitrust Litig.*, 2007 WL 2253425, at \*14 (E.D. Pa. Aug. 3, 2007) (Diamond, J.) (“Plaintiff must establish that each class member has, in fact, been injured by the alleged conduct.”).

Courts reject class certification where impact is not capable of proof at trial through evidence that is common to the class rather than individual to its members. *See New Motor Vehicles*, 522 F.3d at 20 (1st Cir. 2008) (“In antitrust class actions, common issues do not predominate if the fact of antitrust violation and the fact of antitrust impact cannot be established through common proof.”); *Bell Atl. Corp. v. AT & T Corp.*, 339 F.3d 294, 302 (5th Cir. 2003) (“[W]here fact of damage cannot be established for every class member through proof common to the class, the need to establish antitrust liability for individual class members defeats Rule 23(b)(3) predominance.”). As this court has noted, it is “immensely difficult to determine classwide economic impact in indirect purchaser actions.” *OSB Antitrust Litig.*, 2007 WL 2253425, at \*14. That is precisely the case here.

# **1. Evidence Shows that Members of the Proposed Classes Would Not Be Impacted by a Delay in Generic Entry**

Where the evidence at the class certification stage reveals that a substantial portion of the putative class suffered no impact, certification should be denied. *See, e.g., Sheet Metal Workers*, 2010 WL 285552, at \*2 (denying certification because some class members suffered no impact);

*Agric. Chems.*, 1995 WL 787538, at \*11; *Allied Orthopedic Appliances, Inc. v. Tyco Healthcare Group L.P.*, 247 F.R.D. 156 (C.D. Cal. 2007) (denying class certification in an antitrust case as “class certification is precluded where plaintiffs have not shown that the fact of injury element can be proven for all class members with common evidence.”); *Schoenbaum v. E.I. DuPont De Nemours & Co.*, 2009 WL 4782082, at \*9 (E.D. Mo. Dec. 8, 2009) (denying class certification as “predominance is not satisfied where proof of antitrust impact... calls for an individualized inquiry instead of proof common to the class.”); *Bell Atlantic Corp. v. AT&T Corp.* 339 F.3d 294, 302-03 (5th Cir. 2003) (“we have repeatedly held that where the fact of damage cannot be established for every class member through proof common to the class, the need to establish antitrust liability for individual class members defeats [certification]”); 2 *Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law* § 356d (rev. ed. 1995) (“[T]he fact that some class members may not have been damaged at all generally defeats class certification because the fact of injury, or ‘impact,’ must be established by common proof.”).

Here, the evidence shows that substantial numbers of class members would not have been impacted by a delay in generic entry.

**a. Uninsured Consumers**

Dr. Rausser concedes that where the effective cost to an uninsured patient in the actual world was less than or equal to the projected cost to that patient in Plaintiff’s “but-for” world, that uninsured patient would not have been impacted by a delay in the entry of generic Doryx capsules. Rausser Decl. ¶ 19. Dr. Rausser’s methodology, however, simply ignores the individualized inquiry that would be required to make these determinations.

**i. Uninsured Brand Loyal Consumers Suffered no Impact and Cannot Readily be Ascertained**

It is well known that a subset of physicians and patients stay with the brand even after generic entry, perhaps due to concerns over quality, habit, or a desire for consistency. Dr. Rausser acknowledges this phenomenon.<sup>28</sup> [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

As noted above, courts do not hesitate to reject indirect pharmaceutical classes due to the individual issues presented by brand loyal consumers. *See Sheet Metal Workers*, 2010 WL 285552, at \*25–26 (certification denied where brand-loyal purchasers could not be identified in a formulaic manner). IBEW cannot cure this problem by trying to define brand loyalists out of the classes. Some cases have allowed such carve-outs, but only where the generic in question had actually launched, and brand-loyal consumers could be identified. *See, e.g., Terasozin*, 220 F.R.D. 672, 692 (S.D. Fla. 2004); *In re Relafen*, 221 F.R.D. 260, 272–73 (D. Mass. 2004); *Cardizem*, 200 F.R.D. at 343, 347; *Sheet Metal Workers*, 2010 WL 285552, at \*6–7 (Wellbutrin SR). No such real-world data exists here because the generic IBEW posits, the generic Doryx capsule, never came to market in significant quantities.<sup>29</sup>

<sup>28</sup> Rausser Nexium Decl. ¶¶ 90–91 (“Peer-reviewed literature has established that a substantial segment of customers in the pharmaceutical market are brand loyal.”). Dr. Rausser noted a study identifying “subjective and objective” reasons for brand loyalty, including perceived “differences in quality control [between brands and generics]” and evidence that “many US doctors believe brand drugs to be more reliable.” *Id.* ¶ 94.

<sup>29</sup> Generic *tablets* entered the market in January 2011, as discussed above, but IBEW does not use the tablets experience as a model for its but-for world.

[REDACTED]

[REDACTED]

[REDACTED]<sup>30</sup> [REDACTED]

[REDACTED]

[REDACTED]<sup>31</sup> [REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]<sup>32</sup> [REDACTED]

(Ex. 22).

Dr. Rausser is wrong that identifying “brand loyalists” can be handled by a claims administrator at the end of the case. As shown above, “impact” is part of the class certification determination and cannot be deferred to a claims administrator. *See, e.g., Hydrogen Peroxide*, 552 F.3d at 311 (“Importantly, [antitrust impact] is an element of the cause of action; to prevail on the merits, every class members must prove at least some antitrust impact resulting from the alleged violation.”); *Bell Atl. Corp.*, 339 F.3d at 302. Most fundamentally, how will an uninsured patient prove to a claims administrator that in the but-for world he or she would have purchased a hypothetical generic that never came to market? Dr. Rausser offers no answer.

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<sup>30</sup> [REDACTED]

<sup>31</sup> [REDACTED]

<sup>32</sup> [REDACTED]

**ii. Uninsured Patients Utilizing Coupons and Free Samples Suffered no Impact and Cannot Readily be Ascertained**

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]<sup>33</sup> [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Dr. Rausser has recognized the importance of evaluating the effect of coupons on impact and damages. *See* Feb. 27, 2013 Trial Transcript at 192:3–5, *In re Flonase*, 284 F.R.D. 207 (Ex. 23) (“And if you didn’t take [coupons] into account, you would miss the ultimate assessment of common impact, and miss accurately measuring damages.”).

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<sup>33</sup> [REDACTED] (Ex. 13).

But he makes no attempt to undertake such an analysis, therefore he cannot identify consumers that would not have suffered impact because of the coupon program.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**b. Insured Consumers**

**i. Insured Brand Loyal Users Suffered no Impact and Cannot Readily be Ascertained**

The same analysis regarding brand loyal uninsured patients (*see supra* part III.C.1.a.i) holds true for brand loyal patients who have insurance. [REDACTED]

[REDACTED]

[REDACTED]<sup>34</sup> Defendants' expert economist, Dr. Cremieux, assessed the likely magnitude of insured brand loyal users. [REDACTED]

[REDACTED]

[REDACTED],<sup>35</sup> [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Further, Dr. Cremieux estimated that even if only 5% of insured Doryx consumers across the nation were brand loyal (a low estimate

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<sup>34</sup> [REDACTED]

<sup>35</sup> [REDACTED]

in light of the data), that would translated into over 47,500 proposed class members who would not have been impacted by a delay in generic entry. Cremieux Decl. ¶ 32. For the same reasons as noted above, the presence of these unidentifiable but substantial numbers of brand loyal users makes certification impossible.<sup>36</sup>

**ii. Insured Patients with Flat Co-Pays Suffered No Impact and Cannot Readily be Ascertained**

Dr. Rausser concedes that consumers whose insurance required “a single, flat co-pay for both brand and generic drugs . . . were not harmed” by a delay in generic entry “because their cost was the same for the brand and generic drugs.” Rausser Decl. ¶ 107; *see In re K-Dur Antitrust Litig.*, 2008 WL 2660723, at \*11 (D.N.J. Mar. 27, 2008) (recognizing that consumers with “no co-pay or a flat co-pay” would not suffer out-of-pocket loss from alleged antitrust violation). From formulary coverage data, Dr. Cremieux estimates that patients with flat co-pays ranged annually from 8.2% to 15% in Florida, and from 5.4% to 14.6% in Nevada. Cremieux Decl. ¶ 35 and Exhibits 3.1–3.3. This translates to thousands of insured Doryx patients. Cremieux Decl. ¶ 35. In fact, Dr. Rausser opposed certification of a nearly identical end-payer class in the Nexium litigation on the grounds that a “covered consumer’s co-pay is *not predictable*” and depends on “the consumer’s particular prescription drug plan and the date when the purchase was made.” Rausser Nexium Decl. ¶ 42 (emphasis added). Once again, insured consumers with flat co-pays represent a substantial group of patients in the proposed classes who would have suffered no injury—but who cannot be identified formulaically. As with the above issues, the class should be denied for this reason as well.

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<sup>36</sup> [REDACTED]

**iii. Insurance Caps and Formulary Placement Require Individualized Inquiry to Determine Impact**

Many insurance plans offer prescription drug coverage whereby the consumer in some instances has no out of pocket expenses for a prescription, brand or generic. For example, some plans set deductibles or levels of out of pocket expenses that, once reached, insulate the insured consumer from any further costs for prescription drugs. Consumers who have reached such maximum amounts would suffer no injury due to a delay in generic entry. Cremieux Decl. ¶ 39 (discussing examples from different IBEW chapters). The OptumHealth data shows that over 2,000 patients would not be injured in the but-for world because they obtain their Doryx prescriptions at no cost, possibly because they had met their deductible out-of-pocket limit. *Id.* Data from the Kaiser Family Foundation, a source used by Dr. Rausser, likewise suggests that a substantial number of insured consumers had the benefit of such caps.<sup>37</sup> *Id.* at ¶ 39. Moreover, the only way to identify these individuals would be first to identify the plans that offered such coverage for each year in the damage period. Then, for plans with deductibles to determine whether and when—in each year—each individual patient under such plan reached her out of pocket maximum cost / deductible. *Id.* ¶ 39. Dr. Rausser fails to address these issues, let alone provide a formulaic way for identifying these individuals.

Dr. Rausser also fails to consider plans with formularies like the one used by IBEW.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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<sup>37</sup> Kaiser Surveys, at 149 (stating that “11% of covered workers with coverage for prescription drugs are in plans with a separate prescription drug annual out-of-pocket limit”).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Dr. Rausser fails to consider this category of patients and provides no formulaic methodology for identifying and excluding such patients from the class.

**iv. No Injury to Thousands of Coupon Users**

In many instances, insured patients used a Warner Chilcott coupon to reduce their co-payment to zero, which certainly is less than (or equal to) the co-payment Dr. Rausser assumes for generic Doryx in the “but-for” world. From prescription-level data, Dr. Cremieux determined that there were over 300,000 Doryx prescriptions for which insured consumers paid nothing for their prescriptions. Cremieux Decl. ¶ 44 and Exhibit 7. As noted previously, however, Dr. Rausser ignored the impact of these coupons and offers no methodology for identifying such consumers. [REDACTED]

[REDACTED]

[REDACTED]. For each coupon program, an individualized inquiry would be required to determine whether insured coupon users would have been injured. In each instance, the consumer’s net payment would need to be compared to the payment they would have faced had they purchased a generic instead (recognizing that some would not have purchased a generic even had one been available). Cremieux Decl. ¶ 44. For example, Dr. Cremieux estimates that over 129,000 consumers who paid \$10 or less for Doryx as a result of a Warner Chilcott coupon likely were not injured, because their generic co-pay (estimated on average to be \$10) would have been equal to or

greater than their actual out-of-pocket expense for Doryx.<sup>38</sup> Cremieux Decl. ¶ 45. Dr. Rausser proposes no methodology at all for identifying and excluding such proposed class members whose co-pays were reduced. Rausser Decl. ¶ 127; Cremieux Decl. ¶¶ 19–20, 51.

**c. Third Party Payers (TPP's)**

The TPP portion of the proposed class fares no better than the two consumer segments with respect to assessing impact on a formulaic, classwide basis. The problems in this regard are all ones that Dr. Rausser himself acknowledged in his work in the Nexium litigation. Setting aside the fundamental question of ascertaining which TPPs would be in the class given the complex web of risk-sharing that exists among TPPs and plan sponsors (discussed *infra* § III.F.2), individualized analysis would be required to assess whether any particular TPP would have been harmed by a delay in generic entry.

To determine whether any TPP was impacted, as Dr. Rausser has admitted, one must first understand the nature of the financial responsibility being shouldered by the TPP, the level of manufacturer rebates the TPP is receiving, directly or indirectly, with respect to Doryx, the co-payment (or other cost sharing) imposed on insured patients for Doryx under the relevant insurance plan, the benefits of free samples received by plan members, and how all of these many attributes may vary in the but-for world. Rausser Nexium Decl. ¶ 46. Dr. Rausser has proposed no classwide methodology for evaluating any of these factors.

**i. Each TPP's Risk Sharing Arrangements Would Have to be Assessed to Determine Impact**

Identifying whether and to what extent a TPP is “at risk” for a pharmacy benefit is central to evaluating impact, but Dr. Rausser proposes no methodology for undertaking this inquiry.

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<sup>38</sup> As noted above, Dr. Rausser's analyses also should have (but did not) evaluated the impact of free samples on the net price paid by consumers. *See supra* part II.E.2.

[REDACTED]

[REDACTED]

[REDACTED] The nature and extent of such arrangements vary greatly, and can have tremendous implications for whether a TPP has been impacted by a delay in generic entry. Plaintiff concedes that “fully insured health plans” that is, plans that transferred “100% of the plan’s reimbursement obligations” to another TPP through an insurance contract, would not have been impacted and thus must be excluded from the class. IBEW Brief at 2. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Dr. Rausser apparently assumes that risks associated with Medicare Part D prescriptions are borne by private TPPs. The federal government, however, bears the majority of the risk for

Medicare Part D prescriptions.<sup>39</sup> Dr. Rausser agrees that government funded prescriptions are excluded, *but he proposes no methodology for identifying such reimbursements.*<sup>40</sup>

**ii. Many TPPs Suffered No Impact because the Alleged Savings from Generic Doryx Would Have Been Offset by the Loss of Manufacturer Rebates and the Reduction In Cost Sharing from Insured Patients**

The cost to TPPs varies based on the reimbursement rate paid to pharmacies, the rebates received from the drug manufacturer, the amount of cost sharing with the insured consumer (e.g., the insured consumer's co-pay), and the use of samples (which reduces overall cost of therapy for the insured patient.) Rausser Nexium Decl. ¶ 44-45. Of particular significance are manufacturer rebates. [REDACTED]

[REDACTED]

[REDACTED]<sup>41</sup> [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] As Dr. Rausser conceded in Nexium, “[t]ypically, the greater the individual consumer’s co-pay, the less the effective cost to the third party payer.” Rausser Nexium Decl. ¶ 80.

These factors are particularly important where, as here, the difference between the brand and generic price was not substantial. As Dr. Rausser has explained, if the difference between the brand and generic co-pays and the loss of the manufacturer rebate is greater than the

<sup>39</sup> Cremieux Decl. ¶ 61.

<sup>40</sup> *Id.*

<sup>41</sup> Cremieux Decl. ¶ 109; [REDACTED]

[REDACTED] attached as Ex. 25); [REDACTED]  
[REDACTED] (Ex. 26).

difference between the brand and generic reimbursement price borne by the TPP, then the TPP is not harmed. Rausser Decl. ¶ 111;<sup>42</sup> *see In re K-Dur*, 2008 WL 2660723, at \*11 (finding no impact in part because “the difference between the price of branded K-Dur and the generic alternative may be less than the difference between the higher co-pay a TPP receives for branded K-Dur and the lower co-pay the TPP receives for the generic alternative”). In fact, Dr. Cremieux’s analysis of OptumHealth data identified scores of examples where TPPs paid roughly the same or less for Doryx 100 mg tablets than they did for its generic counterpart. Cremieux Decl. ¶ 74. This analysis did not even consider other factors (such as the effect of samples) which would have lowered the net effective cost of Doryx (but not the generic) even further. Cremieux Decl. ¶ 68.

Dr. Rausser eschews this real-world data in favor of his assumption that the but-for world would feature multiple generic entrants starting in July 2006. This allows him to argue that the spreads between the prices for Doryx and generic Doryx in his but-for world would have been large enough to make up for the lost rebates from Warner Chilcott and the reduced co-payments from insured patients. But, as discussed above, his assumptions on generic entry are totally unsupported. *See supra* part III.C.2.c.

Aware that this issue is a problem even with his (unsupported) but-for world assumptions, Dr. Rausser performs a slanted “sensitivity analysis” which he claims establishes that the rebate / co-pay effects would not lead any TPP to be worse off reimbursing for generic Doryx.<sup>43</sup> This analysis provides no cover for Dr. Rausser’s flawed conclusions. First, although he does not acknowledge it, his own sensitivity analysis shows periods in which TPPs *would be*

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<sup>42</sup> The first AB-rated generic to enter the market typically prices its product at a relatively small discount to the brand until other generics enter the market. Cremieux Decl. ¶ 74.

<sup>43</sup> Rausser Decl. ¶ 108.

worse off reimbursing for generic Doryx. Cremieux. Decl. ¶ 65. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].<sup>44</sup> Of course, focusing on averages obscures much individual variation and, in this case, instances of his own analysis disclosing no impact.

Second, his sensitivity analysis only focuses on two factors—rebates and co-pays—that can influence a TPP’s costs. But, as Dr. Cremieux’s analysis shows, several other factors affect whether a TPP was impacted.<sup>45</sup> For example, timing is important, because even under Dr. Rausser’s analysis, damages to TPPs would be negative during certain periods of time, and plans that only reimbursed Doryx in those periods would not be injured.<sup>46</sup> These are not “anomalies” as Dr. Rausser suggests, but instead, were observed by Dr. Cremieux for multiple plans in the OptumHealth data.<sup>47</sup> Moreover, several other factors also impact the cost to TPPs, such as free samples from Warner Chilcott, deductibles, prescription benefit maximums, and the use of preferred pharmacy networks.<sup>48</sup> Dr. Rausser accounts for none of these factors, most of which he conceded in Nexium should be included in any analysis of a TPPs costs. Rausser Nexium Decl. ¶ 45.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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<sup>44</sup> [REDACTED]

<sup>45</sup> Cremieux Decl. ¶ 63–69.

<sup>46</sup> *Id.* ¶ 65–67.

<sup>47</sup> *Id.* ¶ 66.

<sup>48</sup> *Id.* ¶ 67.

Third, even when limited to an examination of only rebates and co-pays, Dr. Rausser's own sensitivity analysis shows TPPs would not be impacted using different assumptions regarding generic entry. Assuming a generic-to-brand price ratio of 80% (a ratio consistent with those used in materials cited by Dr. Rausser), Dr. Rausser's sensitivity analysis would yield cumulative *negative damages* from -\$126 million to -\$193 million, across the three scenarios he modeled.<sup>49</sup> If anything, Dr. Rausser's sensitivity analysis underscores the fact that an individualized inquiry would be required to assess impact of individual TPPs.

### iii. Brand Loyal Consumers Lead to No Impact to TPPs

As discussed above, brand loyal insured consumers suffered no injury. Similarly, TPPs suffered no injury when reimbursing prescriptions filled by brand loyal consumers, because the cost in the but-for world would be the same as (or potentially higher than) the cost in the actual world.<sup>50</sup> In fact, that is precisely the case for IBEW, which has never reimbursed a prescription for generic Doryx. Absent evidence that a TPP did in fact reimburse for generic Doryx in the actual world, there is no basis to infer that the TPP would have reimbursed for the generic (and thus potentially suffered injury) in the but-for world.<sup>51</sup> See *In re Flonase*, 284 F.R.D. at 216 (excluding TPPs that reimbursed brand but never reimbursed for generic); *In re Wellbutrin XL Antitrust Litigation*, 282 F.R.D. at 126 (same).

Here, the data show that a substantial number of TPPs had only brand loyal members. As Dr. Cremieux explains, the real-world data show that 22% of TPPs in the OptumHealth dataset *never reimbursed a single generic Doryx prescription* through the first quarter of 2012,

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<sup>49</sup> Cremieux Decl. ¶ 75.

<sup>50</sup> Cremieux Decl. ¶ 71.

<sup>51</sup> *Id.* ¶ 72.

despite the fact that Mylan launched its 75/100 mg tablets in January 2011.<sup>52</sup> Further, the real-world data also show TPPs and pharmacies did not push patients to the Mylan 75/100 mg tablets, even though it was AB-rated and thus fully substitutable for Doryx tablets of the same strength, and TPPs and pharmacies easily could have driven utilization to the Mylan tablets. These facts refute Dr. Rausser's assertion that generic erosion would be substantially greater in the "but-for" world and show instead that many TPPs likely would suffer no impact.

**iv. TPPs not Impacted Where They Pass on Price Increases Through Premiums**

IBEW asserts claims under Florida and Nevada state laws. Florida recognizes the "pass-on" defense to an overcharge claim, that is, that a plaintiff was not harmed if it was able to pass on all or part of an overcharge to its customers downstream. *See, e.g., In re TFT-LCD (Flat Panel) Antitrust Litig.*, 2013 WL 1010389, at \*2 (N.D. Cal. Feb. 6, 2013) (recognizing that no Florida case law precludes the pass-on defense under the FDUTPA). Nevada has legislation repealing the indirect purchaser rule, with no limitation on pass-on defenses. *See* NEV. REV. STAT. 589A.210(2).

Like any insurance company, TPPs generally pass on their costs in the form of premiums.<sup>53</sup> TPPs usually do this by setting premiums that are expected to be sufficient to cover future medical costs reimbursable under the terms of the plan. Insurers often predict likely future medical costs for plan members by analyzing actual costs incurred in the past (often referred to as "experience rating"). Cremieux Decl. ¶ 70. To the extent TPPs perceived their costs increasing because of a delay in generic entry, they would have raised their premiums for future periods, and thus passed on any alleged overcharge, resulting in no harm to the TPPs. *See*

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<sup>52</sup> Cremieux Decl. ¶ 72; *see also id.* ¶ 73 (hundreds of TPPs nationwide likely only had brand loyal users).

<sup>53</sup> *Id.* ¶ 70.

*Ironworkers Local Union v. Astrazeneca Pharm.*, 634 F.3d 1352, 1364–65 (11th Cir. 2011) (discussing premium setting process); *Blue Cross & Blue Shield of N.J., Inc. v. Philip Morris, Inc.*, 138 F. Supp. 2d 357, 360 (E.D.N.Y. 2001) (“Insurance companies . . . are financial intermediaries that set their rates so as to cover all anticipated claim costs. . . . [A]s costs increase, from whatever source, insurers can pass the majority of these costs onto the insurance buyers through subsequent premium increases.”); *Int’l Bhd. of Teamsters v. Philip Morris Inc.*, 196 F.3d 818, 824 (7th Cir. 1999) (TPPs “are just financial intermediaries”); Cremieux Decl. ¶ 70. Individualized inquiry would be needed, then, for the Florida and Nevada classes, as to whether the TPPs passed on all or part of any assumed overpayment for Doryx. Dr. Rausser did not even attempt to analyze this issue. Assessing pass-on is an inherently individualized undertaking. *See, e.g., Illinois Brick Co. v. Illinois*, 431 U.S. 720, 741 (1977) (discussing complexities of assessing pass-through).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] This is yet another reason why IBEW is an inadequate class representative.

**v. The Timing of Each Reimbursement and the Provisions of Each Health Plan Create No-Impact Situations**

Even where plan members may purchase a generic Doryx product in the but-for world, TPPs may require patients to meet a deductible limit before the TPP will reimburse any portion of the cost of a prescription. If a plan member has not met his or her deductible—or if the

deductible applied only to brand name drugs, with the TPP sharing in some of the cost of generic prescriptions—the TPP would suffer no impact. Cremieux Decl. ¶ 76.

\* \* \*

As this court has noted, where the evidence shows that some members of the proposed class would not have paid increased prices “this suggests that plaintiffs will have to prove economic impact customer by customer, exactly what the [Third Circuit] condemned [in *Linerboard*].” *OSB Antitrust Litig.*, 2007 WL 2253425, at \*21. Such is the case here.

**d. IBEW Cannot Defer the Difficult Issues to a “Claims Administrator” at the End of the Case**

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] However, as noted, impact is “critically important for purposes of evaluating Rule 23(b)(3)’s predominance requirement because it is *an element of the claim* that may call for individual, as opposed to common, proof.” *Hydrogen Peroxide*, 552 F.3d at 311 (emphasis added); *Blue Bird Body Co.*, 573 F.2d at 327 (common evidence must allow “*each* plaintiff [in the proposed class] . . . [to] prove . . . injury”) (emphasis added); *OSB Antitrust Litig.*, 2007 WL 2253425, at \*19 (same). Put simply, such difficult impact issues cannot be kicked down the road, as Dr. Rausser suggests.

**2. Dr. Rausser’s “Findings” are Dependent on a Daisy Chain of Assumptions and/or Unsupported Conclusions**

The courts are clear that the critical Rule 23 showings—such as whether impact as to each class member can be shown with common evidence—cannot be based on assumptions or the *ipse dixit* of an expert. This Court has warned that expert testimony must be tethered to the “real economic world.” *OSB Antitrust Litig.*, 2007 WL 2253425, at \*29. And in *Comcast*, the Supreme Court likewise condemned certifications based on “speculative” and “arbitrary” showings by plaintiff. *Comcast*, 133 S. Ct. at 1433; *see also Eastman Kodak Co. v. Image Tech. Servs. Inc.*, 504 U.S. 451, 466-67 (1992) (warning that “[l]egal presumptions that rest on formalistic distinctions rather than *actual market realities* are generally disfavored in antitrust law.”) (emphasis added); *Agric. Chems.*, 1995 WL 787538, at \*5 (denying certification when plaintiffs’ expert, without considering evidence to the contrary, “merely assume[d] that [damage to each class member] took place”); *Paul B. Moore v. Southeast Toyota Distrib., Inc.*, 1982 WL 1841, at \*4 (S.D. Ala. Feb. 4, 1982) (same); *Sample v. Monsanto Co.*, 218 F.R.D. 644, 651 (E.D. Mo. 2003) (same); *In re Plastics Additives Antitrust Litig.*, 2010 WL 3431837, at \*19 (E.D. Pa. Aug. 31, 2010) (expert opinion unreliable when “his regressions are not necessarily representative of individual class member experience, and unrefuted evidence shows that some class members suffered impact while others did not”).

In fact, Dr. Rausser’s opinions have been rejected by courts for failure to link his conclusions with the actual facts of the case. *See In re Se. Milk Antitrust Litig.*, 801 F. Supp. 2d 705 (E.D. Tenn. 2011) (Dr. Rausser criticized for ignoring economic realities of raw milk market); *Allen v. Dairy Farmers of Am., Inc.*, 2011 WL 6148678 (D. Vt. Dec. 9, 2011) (Dr. Rausser’s common impact analysis was “fundamentally flawed” because it ignored important variables); *In re Potash Antitrust Litig.*, 954 F. Supp. 1334, 1389 (D. Minn. 1997) (stating that

Dr. Rausser’s “opinions can be no more reliable than the factual underpinnings upon which they have been predicated” and discounting his opinions accordingly); *In re High Fructose Corn Syrup Antitrust Litig.*, 156 F. Supp. 2d 1017, 1054 (C.D. Ill. 2001) (Dr. Rausser’s reliance on “assumptions or inferences that the Court has found to be not reasonably supported by the record . . . does not tip in favor of the Plaintiff class or demonstrate that a hypothesis of collusion is more plausible than a hypothesis of individual action.”); *Oxygenated Fuels Ass’n v. Pataki*, 293 F. Supp. 2d 170, 181 (N.D.N.Y. 2003) (Dr. Rausser’s testimony is “speculative and has insufficient evidentiary support and . . . therefore plaintiff has not made its case regarding the economic impacts.”).

Dr. Rausser’s conclusions regarding common impact suffer from the same willful blindness to the realities of these classes and this marketplace.

**a. Dr. Rausser Wrongly Assumes that Warner Chilcott’s New Products Represent “Immaterial” Changes Over Prior Versions**

The key to IBEW’s entire theory of common impact is the proposition that, as Dr. Rausser put it, Warner Chilcott’s new Doryx products represented “immaterial” changes to prior versions. If the new introductions in fact *were* improvements, then, by IBEW’s own theory, they cannot be viewed as anticompetitive, *and* IBEW would have no basis to pretend that the products would not have been introduced in the but-for world.<sup>54</sup>

Tellingly, though, IBEW offers no *evidence* that Warner Chilcott’s new products were not improvements. It offers no scientific material, testimony from physicians, pharmacists or anyone competent to address the medical merits of the Warner Chilcott products. Dr. Rausser is

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<sup>54</sup> As noted, Warner Chilcott disagrees that a company should face antitrust risk at all based on whether a new product represents an improvement over prior versions.

an economist, not a dermatologist or scientist, so he is not competent to do so.<sup>55</sup>

Instead of addressing the medical/scientific merits of Warner Chilcott's products, IBEW (and Dr. Rausser) quote from Warner Chilcott documents referencing an "anti-generic" strategy. As an initial matter, there is nothing improper about having a strategy "anti" to your competitors. In fact, the very purpose of the antitrust laws is to foster tough, aggressive competition. *See, e.g., RJ Reynolds Tobacco Co. v. Cigarettes Cheaper!*, 462 F.3d 690, 696 (7th Cir. 2006) (internal citations omitted) ("[A]s we remark frequently in antitrust litigation, 'cutthroat competition' is a term of praise rather than condemnation. . . . Businesses need not love their rivals (or firms that compete with their customers. . . ."); *Answerphone, Inc. v. Bell Atl. Corp.*, 955 F. Supp. 418, 432 (W.D. Pa. 1996). Coke has an "anti-Pepsi" strategy, and McDonalds has an "anti-Burger King" strategy—and the antitrust laws encourage it. Thus, the mere fact that Warner Chilcott had a desire to stay ahead of its generic competitors says nothing about whether its conduct was lawful, but more importantly for present purposes, it says nothing about whether its new Doryx products were improvements over the old.

As *Comcast* teaches, IBEW bears the burden of proving with *evidence* that the assumptions underlying its certification conclusions are justified. It has utterly failed to do so here.<sup>56</sup>

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<sup>55</sup> Rausser asserts that Warner Chilcott's 75/100 mg tablets must not have been a medical improvement because the company did not price them higher than the prior capsule versions, Rausser Decl. ¶ 43, and makes a similar point about the 150 mg tablets. *Id.* ¶ 47. However, as illustrated by cell phone and tablet markets, truly better products are introduced all the time that are not priced at a premium. Moreover, the pricing of Warner Chilcott's brands were also disciplined by the brands against which it competed, something Dr. Rausser did not analyze at all. Rausser Dep. Tr. 53:1–56:15 (admitting he did not perform a cross elasticity analysis); Cremieux Decl. ¶ 80.

<sup>56</sup> Having failed to offer evidence in its opening submission, IBEW cannot be permitted to surface with medical or other evidence on reply. Such sandbagging tactics are not tolerated by the courts. *See Laborers' Int'l Union v. Foster Wheeler Energy Corp.*, 26 F.3d 375, 398 (3d Cir. 1994) ("[a]n issue is waived unless a party raises it in its opening brief, and for those purposes 'a passing reference to an issue . . . will not suffice to bring that issue before this court.'" (citations omitted).

In fact, there are clear medical and other advantages to Warner Chilcott's new products. From the standpoint of the physician, as explained by Dr. Guy Webster, a dermatologist who has been practicing for more than twenty years, and is the Founding President of the American Acne and Rosacea Society, Warner Chilcott's Doryx tablet products, among other things, offered a reduction in esophageal injuries associated with Doryx capsules; flexibility in creating and altering treatment regimens (with the flexibility to split tablets and to crush and sprinkle applesauce); increased ease in complying with treatment regimens; and a reduction in co-payments and reimbursements by third party payors.<sup>57</sup>

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]<sup>58</sup> [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]<sup>59</sup>

Professor Bhaskara Jasti, the chair of the Department of Pharmaceuticals and Medicinal Chemistry at University of the Pacific, submits a declaration discussing many of the same advantage and also noting that Doryx tablets had improved stability and shelf-life (24 months versus 12 months for capsules).<sup>60</sup>

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<sup>57</sup> Declaration of Guy Webster, M.D. ¶¶ 1–12, 20.

<sup>58</sup> [REDACTED]

<sup>59</sup> [REDACTED]

<sup>60</sup> Jasti Decl. ¶¶ 67–69.

And, of course, the original move from Doryx capsules to tablets allowed Warner Chilcott to avoid the kind of esophageal side effects that led Doryx to being withdrawn from the market in Sweden.<sup>61</sup> See Webster Decl. ¶¶ 63–68; *see also id.* at ¶¶ 70–71 (French government recommending that tetracycline antibiotics move from capsule to tablet form due to esophageal adhesion). Finally, a plethora of public sources underscore the medical and business benefits associated with Warner Chilcott’s follow-on Doryx products.<sup>62</sup> See, e.g., Webster Decl. ¶¶ 72–80 (collecting medical literature on esophageal injuries caused by doxycycline (Doryx) capsules).

In short, IBEW’s (and Dr. Rausser’s) assumptions aside, there can be no doubt that the Warner Chilcott Doryx products offered “clinical or medical benefits over prior formulations.” This fact alone, which the Court must consider at the class certification stage (per *Comcast*), completely undermines IBEW’s common impact theory.

**b. Dr. Rausser Wrongly Assumes that Warner Chilcott would Not Pursue “Next-Generation” Doryx products if Generic Capsules had Entered in 2006**

Another linchpin to Dr. Rausser’s conclusion of classwide impact is the assumption that Warner Chilcott would stop innovating if generic Doryx capsules had entered in significant

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<sup>61</sup> [REDACTED] (Ex. 27); *see also* S. Abid, K. Mumtax, et al., *Pill-Induced Esophageal Injury: Endoscopic Features and Clinical Outcomes*, 37 *ENDOSCOPY* 740 (2005) (study between 1997 and 2003 showed 92 patients suffered from esophageal injuries, most commonly from tetracyclines, including doxycycline); Mohammed A. Al-Mofarreh, Ibrahim A. Al Mofleh, *Esophageal ulceration complicating doxycycline therapy*, 9(3) *WORLD J. GASTROENTEROLOGY* 609 (2003) (reporting 36 patients from one clinic with esophageal ulcerations caused by doxycycline capsules).

<sup>62</sup> See, e.g., Guidance for Industry: Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation, U.S. Food and Drug Administration (2013) (“Consistent scoring ensures that the patient is able to adjust the dose, by splitting the tablet, in the same manner as the RLD [reference listed drug]. This enables the patient to switch between products made by different manufacturers without encountering problems related to the dose. In addition, consistent scoring ensures that neither the generic product nor the RLD has an advantage in the marketplace because one is scored and one is not.”); Best Practices for Tablet Splitting, U.S. Food and Drug Administration (2009) (advising patients to consult with healthcare providers before splitting tablets given weight variations associated with pill splitting); [REDACTED]

quantities in 2006 (as he assumed they would). But, again, neither Dr. Rausser nor IBEW offers any *evidence* to support this assumption. When asked at his deposition, Dr. Rausser said he assumed that Warner Chilcott would have no incentive to pursue a new formulation after an assumed generic capsule launch, but he offered no analysis or evidence to support this view.<sup>63</sup>

Again, the evidence points in the other direction.

Perhaps the strongest indication that Warner Chilcott would not have abandoned its Doryx franchise in the face of generic competition is found in its real-world conduct with respect to its 200 mg Doryx tablet product. Warner Chilcott filed its application for the 200 mg tablet in 2009, before any generic Doryx tablet was on the market. Although Mylan entered with generic tablet versions beginning in January 2011, Warner Chilcott did *not* abandon the 200 mg tablet as Dr. Rausser's hypothesis would suggest. Instead, it continued to pursue the application, which FDA approved just a few weeks ago. [REDACTED]

[REDACTED]. Indeed, Warner Chilcott's competitors were marketing their tablet products *against* Doryx based on the problems associated with capsules (e.g., esophageal irritation, recall in Sweden, tendency of Doryx capsules to stick in throat).<sup>65</sup> [REDACTED]

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<sup>63</sup> Rausser Dep. Tr. 201:1–16.

<sup>64</sup> [REDACTED]

<sup>65</sup> See Webster Decl. ¶ 52–84; [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED] [REDACTED]

[REDACTED]<sup>66</sup> Despite this, Medicis experienced success with its Dynacin tablet.<sup>67</sup> Such a precedent, of course, not only would have been relevant to Warner Chilcott's thinking but also undercuts Dr. Rausser's assumption that a brand company would have no interest in pursuing a line-extension after generic entry.

Moreover, Warner Chilcott secured issuance of the '161 patent in 2005. As noted, that patent covered an improved, more stable, version of the enteric-coated pellets used in Doryx capsules. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]<sup>68</sup>

As noted, Dr. Rausser's but-for world is one without any follow-on Doryx products from Warner Chilcott. The above evidence serves as further confirmation that Dr. Rausser's assumption is baseless, and so too are his conclusions regarding classwide impact.

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<sup>66</sup> [REDACTED]

<sup>67</sup> [REDACTED]

<sup>68</sup> [REDACTED]

**c. Dr. Rausser Wrongly Assumes that Multiple Generic Competitors would be Ready, Willing and Able to Launch Generic Doryx Capsules in July 2006**

In addition to his unsupported assumptions regarding the Doryx tablet products, Dr. Rausser also reaches unsupported conclusions regarding the entry of generic Doryx capsules. Cremieux Decl. ¶¶ 86–91. As noted, Dr. Rausser assumes “at least half a dozen” generic firms would have entered with capsules products in or around July 2006. Rausser Decl. ¶ 21. Dr. Rausser claims Sandoz would have been able to “serve the market” in July 2006 (Rausser Decl. ¶ 122) and that other—albeit unidentified—generic manufacturers would have entered at that point or shortly thereafter. [REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]<sup>69</sup> [REDACTED]

[REDACTED]

[REDACTED]<sup>70</sup> The mere fact that no generic firm apparently pursued an ANDA on Doryx capsules in the nearly twenty years between 1985 (when the capsules were launched) and December 2004 (when Sandoz filed its ANDA) undercuts the idea of half a dozen or more generic firms jumping into the market in mid-2006. Again, Plaintiff has the burden of establishing the reasonableness of its assertions, and unsupported assumptions that are contrary to known facts do not do so. *See, e.g., Comcast*, 133 S. Ct. at 1438–39.

<sup>69</sup> [REDACTED]

<sup>70</sup> [REDACTED]

In fact, the evidence shows that the only two generic firms to seriously consider Doryx capsules ANDAs had various formulation and manufacturing issues that call into question Dr. Rausser's assumption that even two generics, let alone at least half a dozen, would have been able to enter and fully serve the market beginning in 2006. *See, e.g., Jasti Decl.* ¶ 75–125. Warner Chilcott incorporates the detailed discussion of this evidence found in its DPP Opposition Brief. DPP Opp. Br. at III.C.

**3. Dr. Rausser's Model for Assessing Common Impact Ignores IBEW's own Liability Theory, Economic Realities, and Makes no Attempt to Filter Effects Caused by Competition-Enhancing Activities**

*Comcast* makes clear that a model used to support class certification must take account of economic realities *and* must be able to filter out the price effects of competition-enhancing (or at least competition-neutral) conduct. *See Comcast*, 133 S.Ct. at 1433–35. Dr. Rausser's model here fails in both respects.

**a. Dr. Rausser's "Overcharge" Theory does not Comport with Economic Reality as to the TPP Members of the Classes**

Dr. Rausser proposes to measure an overcharge by comparing the average prices of branded Doryx *tablets* with the prices of generic Doryx *capsules* that would have been available in the but-for world. However, it is clear that there are medical differences between Doryx tablets and generic capsules—the most obvious difference being that FDA does not classify Doryx tablets as “AB” as against Doryx capsules, meaning that they are not automatically substitutable with one another. There also are clear differences between the capsules and tablets associated with dosing flexibility, risk of gastrointestinal side effects, and the like, as discussed above. *See supra* part II.C. Since Doryx tablets and capsules are not the same, the tablet-capsule price difference is not an economically meaningful measure of harm for TPPs that pay for the drug, then recoup their costs through the premiums they collect. *Cremieux Decl.* ¶¶ 70, 100.

The economically appropriate measure of damages for such TPPs would be the profits, if any, lost due to the claimed delay in generic Doryx capsules. Warner Chilcott incorporates the more detailed discussion of this issue found in the DPP Opposition Brief. DPP Opp. Br. at III.B.

If viewed, as it should be, in lost profits terms, the TPP class could not be certified. It is well known that lost profits cases involve individualized analysis and are not suitable for class action treatment. *See Lazy Oil, Co. v. Witco Corp.*, 95 F. Supp. 2d 290, 303 (W.D. Pa. 1997); *see also Broussard v. Meineke Discount Muffler Shops, Inc.*, 155 F.3d 331, 342-44 (4th Cir. 1998); *Bayshore Ford Truck v. Ford Motor Co.*, 2010 WL 415329, at \*11-13 (D.N.J. Jan. 29, 2010).

**b. Dr. Rausser’s “Impact” Model does not Fit IBEW’s Liability Theory**

As discussed, IBEW’s own theory allows that a product representing an “improvement” is not anticompetitive. *See supra* part II.D. Not only has IBEW failed to show that Warner Chilcott’s Doryx products were not improvements, the evidence demonstrates substantial advantages. *Id.* Dr. Rausser consequently was not free to assume away Warner Chilcott’s next generation Doryx products. At most, he was entitled to assume that Warner Chilcott would have continued to make and market the older products even as it introduced and sold the subsequent ones. Cremieux Decl. ¶¶ 78–84. Dr. Rausser’s methodology does not even attempt to address the possibility of “improved” Doryx branded products coming to market in the but-for world. But, as noted, IBEW’s *liability theory* allows for such a possibility. Thus, Dr. Rausser’s attempt to assume out of existence at least seven Warner Chilcott tablet products conflicts squarely with *Comcast’s* teaching that “at the class certification stage . . . any model supporting a ‘plaintiffs’ damages case must be consistent with its liability case, particularly with respect to the alleged

anticompetitive effect of the violation.”<sup>71</sup> 133 S. Ct. at 1433 (quoting ABA SECTION OF ANTITRUST LAW, PROVING ANTITRUST DAMAGES: LEGAL AND ECONOMIC ISSUES 57, 62 (2d ed. 2010)).

If one or more branded Doryx tablet products are assumed alongside generic capsules, then one cannot assume, as Dr. Rausser does, substantial generic erosion and price declines. Cremieux Decl. ¶¶ 83–84. Each physician and consumer would have to decide whether to select generic Doryx capsules, branded Doryx tablets or a different therapy altogether. *Id.* Dr. Rausser’s approach accounts for none of this, and this failure is fatal. As the Supreme Court warned: “[A] model purporting to serve as evidence of damages in [a] class action must measure only those damages attributable to [the impact] theor[ies] [accepted by the court]. If the model does not even attempt to do that, it cannot possibly establish that damages are susceptible of measurement across the entire class for purposes of Rule 23(b)(3).” 133 S. Ct. at 1433.<sup>72</sup>

#### **D. Individual Issues Predominate with Respect to Damages**

##### **1. IBEW’s Model for Calculating Aggregate Damages is Flawed**

As noted above, *Comcast* puts a spotlight on analyzing at the class certification stage the propriety of class plaintiffs’ proposed damages methodology. 133 S. Ct. at 1433. Here, Dr.

<sup>71</sup> [REDACTED]

<sup>72</sup> See also, e.g., *City of Pittsburgh v. West Penn Power Corp.*, 147 F.3d 256, 266 (3d Cir. 1998) (affirming the dismissal of a complaint where “‘utilities’ purported antitrust violation can only be said to have been competition-neutral and as such, is not actionable”) (citing *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 320, 344 (1990)) (“The antitrust injury requirement ensures that a plaintiff can recover only if the loss stems from a competition-reducing aspect or effect of the defendant’s behavior.”); *Pool Water Prods. v. Olin Corp.*, 258 F.3d 1024, 1034 (9th Cir. 2001) (“If the injury flows from aspects of the defendant’s conduct that are beneficial or neutral to competition, there is no antitrust injury, even if the defendant’s conduct is illegal *per se*.”) (citations omitted). And any damages model must properly distinguish between competition-reducing and competition-enhancing (or neutral) aspects of the claimed harm. See *Blue Cross and Blue Shield United of Wisconsin v. Marshfield Clinic*, 152 F.3d 588, 593 (7th Cir. 1998) (“Any nonconspiratorial factors likely to have made the prices charged by the [defendant] higher than the prices charged by other health-care providers had to be taken into account in order to make a responsible estimate of the prices that [plaintiff] would have paid had it not been for the conspiracy.”).

Rausser's proposed methodology—which takes average branded tablet prices, compares them to assumed average prices for generic capsules and applies an assumed generic penetration rate—is rife with problems.

First, in addition to depending entirely on unfounded assumptions about Warner Chilcott's product launches and generic capsule entry in 2006, Dr. Rausser's damage model uses a generic penetration rate from inapposite academic articles. Dr. Rausser bases his estimate on an article regarding the penetration rate for 29 drugs subject to generic entry between 1999 and 2003, but that article did not study any drugs used to treat acne. Cremieux Decl. ¶ 96. [REDACTED] [REDACTED]”<sup>73</sup> relying on a study that does not consider the prescribing habits of this specialty group of physicians is not reasonable.<sup>74</sup> Nor did the study used by Dr. Rausser consider the effect of next generation products launched by the branded drug manufacturer, a complicating factor in this case that Dr. Rausser assumes away. Cremieux Decl. ¶ 96. [REDACTED]

[REDACTED] In short, Dr. Rausser's reliance on academic articles that study different therapeutic areas and entry scenarios is improper. Cremieux Decl. ¶ 98.

Second, Dr. Rausser assumes that total combined brand and generic Doryx sales would have been the same in the but-for world as they were in the actual world, but he provides no support for this assumption. Rausser Decl. ¶ 122. [REDACTED]

<sup>73</sup> [REDACTED]

*See also* Cremieux Decl. ¶ 95.

<sup>74</sup> Cremieux Decl. ¶ 94. The article includes in its sample brand drugs that were subject to entry by five and in some instances ten generic competitors, situations vastly different than this case, and another reason why reliance on averages to predict generic penetration cannot be justified. Cremieux Decl. ¶ 96.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The inevitable withdrawal of promotion in the but-for world would mean *reduced* volume for the “molecule,” rather than the steady volume Dr. Rausser assumes. Indeed, Dr. Rausser’s own data shows a substantial reduction in sales for Doryx 150 mg tablets when Warner Chilcott cut back its couponing, thus confirming the volume shrinkage when promotion is withdrawn. Rausser Decl. fig. 4. Thus, Dr. Rausser’s total damage estimate is overstated by the degree that volume would have decreased in the but-for world.

Third, Dr. Rausser’s use of *average* prices (for both branded tablets and generic capsules) masks individual issues. Cremieux Decl. ¶ 102–03. As Dr. Cremieux showed using state-level prescription data, the prices actually paid by patients in Nevada and Florida varied substantially, and those price variations were not captured by nationwide average data used by Dr. Rausser. *Id.* Using national average data, therefore, as Dr. Rausser proposes, would overcompensate some class members, and undercompensate others. Cremieux Decl. ¶ 103; *see also Espenscheid v. DirectStat USA, LLC*, 705 F.3d 770, 774 (7th Cir. 2013) (decertified class where plaintiffs’ proposed damages model used inaccurate average data that would result in overcompensation of some class members and undercompensation of others).

Dr. Rausser himself recognizes the problems with using averages in a Rule 23 analysis: “Ignoring [price] variability by employing averages or median prices leads to an inaccurate and unfair damage estimate.” Rausser Nexium Decl. ¶ 117; *see also, e.g., id.* at n.50 (criticizing the

practice of “attempting to calculate class-wide damages in reliance on means, averages, or distributions”). In fact, Dr. Rausser was chastised recently for failing to follow his own advice with respect to averages. In *Reed v. Advocate Healthcare*, Dr. Rausser’s opinion in support of certification was rejected, with the court writing that “[t]he first, and critical, flaw is [Rausser’s] reliance on averages.” 268 F.R.D. 573, 590–91. The court warned that using averages in a Rule 23 situation “can hide substantial variation across individual cases, which may be key to determining whether there is common impact.” *Id.* at 591.<sup>75</sup> See also, e.g., *Weiner v. Snapple Beverage Co.*, 2010 WL 3119452, at \*9–10 (S.D.N.Y. Aug. 5, 2010) (rejecting reliance on averages for Rule 23 inquiry); *In re Flash Memory Antitrust Litig.*, 2010 WL 2332081, at \*12 (N.D. Cal. June 9, 2010) (same); *In re Graphic Processing Unit Antitrust Litig.*, 253 F.R.D. 478, 493–94 (N.D. Cal. 2008) (same).

These fundamental flaws require rejection of the proposed classes. See, e.g., *Blades v. Monsanto Co.*, 400 F.3d 562 (8th Cir. 2005) (affirming district court’s denial of class certification based on the finding that individualized issues predominate as to damages); *Rodney v. Northwest Airlines, Inc.*, 146 Fed.Appx. 783 (6th Cir. 2005) (same); *Steering Committee v. Exxon Mobil Corp.*, 461 F.3d 598 (5th Cir. 2006) (same); *Stephens v. Seven Seventeen HB Philadelphia Corp. No. 2*, 2004 WL 1699331, at \*5 (E.D. Pa. July 29, 2004) (denying motion for class certification because individualized issues predominated over common ones).

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<sup>75</sup> While the court in *Flonase* distinguished the criticism of Dr. Rausser in *Reed*, *Flonase* (1) did not have the substantial “no impact” evidence present here, see *supra* III.C.1; Cremieux Decl. ¶¶ 18–19, and (2) was decided before *Comcast* reinforced the need for evidentiary scrutiny of common impact issues. And, indeed, the *Flonase* court did find that “averaging” masked significant differences for uninsured patients and thus refused to certify a class including such individuals. 284 F.R.D. at 230.

**2. IBEW’s Model, at Best, Can Assess only Aggregate Damages, but Cannot Assign Damages to Individual Class Members**

*Comcast* made clear that to satisfy Rule 23(b)(3) the plaintiff must show—at the class certification stage—that “damages are capable of measurement on a classwide basis” and that “individual damages calculations” will not “overwhelm issues common to the class.” 133 S. Ct. at 1433 (requiring “damages [be] susceptible of measurement across the entire class.”). *Comcast* represents a sea change in the law of class certification: whereas many courts had held that individual issues in calculating damages (as distinguished from assessing antitrust “impact”) would not preclude certification, the Supreme Court made clear that Plaintiff must show at the class certification stage that damages are capable of classwide assessments as well. *See Martins v. 3PD, Inc.*, 2013 WL 1320454, at \*8, n. 3 (noting that in *Comcast*, the Supreme Court “has called . . . into question” the proposition that “courts generally find the predominance requirement satisfied even if individual damages issues remain.”).

Dr. Rausser’s approach fails the *Comcast* standard because it seeks to show only that damages can be “calculated in the aggregate.” Mot. at 33. He admits that he has no method for avoiding “individual damages calculations” in the claims administration phase. He just assumes a way will be found to deal with them at that time. But the tactic of calculating aggregated damages to be divvied up later cannot be squared with the teaching of *Comcast*. Indeed, such a “fluid recovery” approach was questionable in this Circuit and elsewhere even before *Comcast*. *OSB Antitrust Litig.*, 2007 WL 2253425, \*14 (stating that “[a]warding damages through fluid recovery is controversial” and “several district courts in this Circuit have condemned it”); *see Windham v. Amer. Brands, Inc.*, 565 F.2d 59, 72 (4th Cir. 1977) (“[T]he difficulties inherent in proving individual damages [cannot] be avoided by the use of . . . “fluid recovery.”); *In re Hotel Tel. Charges*, 500 F.2d 86, 89–90 (9th Cir. 1974); *Eisen v. Carlisle & Jacquelin*, 479 F.2d 1005,

1018 (2d Cir. 1973) (fluid recovery is “illegal, inadmissible as a solution of the manageability problems of class actions and wholly improper”), *vacated on other grounds*, 417 U.S. 156 (1974).<sup>76</sup> *Comcast* makes clear that reliance on an “aggregate” methodology where “individualized damage calculations” nonetheless will be needed is improper.

Moreover, a claims administrator is simply not equipped to deal with the complex “no impact” inquiries reviewed in prior sections. Individualized assessments designed to address these complexities would present precisely the type of labyrinthine calculations rejected by *Comcast* and other courts. For example, as explained above, a host of highly variable consumer and TPP-specific factors affect the net effective prices paid by the three subgroups in both the actual and but-for worlds. These factors include:

- The amount of co-pays / co-insurance and other plan benefit design factors (insured consumers and TPPs);
- The use of manufacturer coupons (insured and uninsured consumers);
- The use of samples (all subgroups);
- Deductibles and coverage limits (insured consumers and TPPs);
- The receipt of manufacturer rebates (TPPs);
- The nature and extent of risk sharing with other entities (TPPs);
- Retail pharmacy reimbursement rates (TPPs); and
- The cash register price at the retail pharmacy, which is affected by markups at the manufacturing, wholesale and related levels (insured and uninsured consumers); and
- The time period when the drug was purchased (all subgroups).

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<sup>76</sup> *In re Pharm. Average Wholesale Price Litig.*, 582 F.3d 156, 197 (1st Cir. 2009) does not help Plaintiff because in that case, unlike here, plaintiff’s damages test “sufficiently incorporated individualized information about the class members to support the district court’s decision to adopt it for the entire class.” *In re Terazosin Hydrochloride*, 220 F.R.D. 672, 699 (S.D. Fla.2004) has been called into question by *In re Relafen Antitrust Litig.*, 221 F.R.D. 260, 287 (D. Mass. 2004), which criticized *Terasozin* for failing to refer to or analyze Florida law and held that Florida law “require[d] a somewhat stronger and more precise showing of individual impact” than the aggregate approach being proposed.”

To assess impact, and ultimately damages, these factors would have to be addressed on an individual basis for each class member and each transaction. (*See supra* III.D (reviewing needed inquiries)).

A similar web of complex, individualized factors would affect the amount of brand and generic purchases in the but-for world. As discussed above (*supra* III.C), these factors include:

- Number of generic entrants and timing of each entry;
- Nature and extent of marketing support for branded and generic products;
- Level of brand loyalty of insured and uninsured consumers; and
- Effects of TPPs driving utilization to generic products through, for example, changes in co-pays, prior authorization requirements, and similar tactics.

Analyzing these variable factors on an individualized basis would be a massive undertaking.

**E. Certification Cannot be Based on Promises to Perform Needed Analyses in the Future**

Dr. Rausser's "analysis" involves mainly deferring difficult questions. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

In short, when all of the assumptions, averages and generalities are stripped away, Dr. Rausser's "analysis" amounts to a promise to figure something out in the future. But basing

class certification on such promises has always been frowned upon by the courts, and it is fatal after *Comcast*. 133 S. Ct. at 1433; *see also, e.g., Windham v. Am. Brands, Inc.*, 565 F.2d at 70 (court “should not certify the class merely on the assurance of counsel that some solution will be found”); *In re Neurontin Antitrust Litig.*, 2011 WL 286118, \*10 (D.N.J. Jan 25, 2011); *In re Wellbutrin SR Direct Purchaser Antitrust Litig.*, 282 F.R.D. 126 (E.D. Pa. 2008).

**F. IBEW Cannot Satisfy Rule 23(a) Requirements**

**1. There is an Inherent Antagonism between IBEW and Members of the Class, and Among Class Members Themselves**

In *Dewey v. Volkswagen*, 681 F.3d 170 (3rd Cir. 2012), the Third Circuit explained that “[a] fundamental conflict exists where some [class] members claim to have been harmed by the same conduct that benefitted other members of the class.” *Id.* at 184 (citation omitted). As discussed above, the proposed classes here are rife with “winners” and “losers” in a world assuming entry of generic Doryx capsules in 2006. Certification is inappropriate in the face of such differing interests.

Moreover, IBEW has little to nothing in common with either the insured or the uninsured consumer members of the proposed classes. IBEW certainly has nothing in common with the *consumer* members of the classes, nor does it (with its 6,000 insureds) have anything in common with insurance giants such as Kaiser Permanente, Blue Cross-Blue Shield, and other sophisticated health insurers covering millions of patients.

Moreover, there are inherent conflicts between the claims of insurance providers, such as IBEW, and insured consumers. For every prescription subject to a claimed overcharge, insurers and insureds will have to split that overcharge between them. Each will have an interest in maximizing its share. IBEW also has an interest in maximizing the allocation of aggregate damages in favor of the TPP segment of the class, to the detriment of the uninsured consumer

segment of the class. Such conflicts alone render IBEW inadequate as a class representative for the proposed classes. *See, e.g., Pickett v. IBP Inc.*, 182 F.R.D. 647, 653 (M.D. Ala. 1998) (“[C]ourts have found that Rule 23 requirements are not satisfied where some class members are given an advantage, while others are put at a disadvantage.”); *Katz v. Comdisco, Inc.*, 117 F.R.D. 403, 408 (N.D. Ill. 1987) (denying class representative status to individual who benefited from alleged activity while class members were harmed); *Auto Ventures, Inc. v. Moran*, 1997 WL 306895, at \*5 (S.D. Fla. April 3, 1997) (rejecting class certification where proposed class representatives may have been forced to argue that they actually benefited by alleged antitrust activity); *Bieneman v. City of Chicago*, 864 F.2d 463, 465 (7th Cir. 1988) (denying class certification where some of the proposed class members “undoubtedly derive great benefit” from the challenged action and proposed class representative, therefore, conflicted with interests of some class members).

There is also an inherent conflict between plan sponsors (like IBEW) and other TPPs over who is “on the risk” for particular reimbursements. Given the myriad risk transfer and risk sharing arrangements among TPPs, there will be conflicts between and among pharmacy benefits managers, claims administrators, full or partially self-funded employers and union funds such as IBEW over who is ultimately financially responsible for any particular prescription reimbursement. As discussed above, the entity that actually reimburses the pharmacy may be performing a simple claims administration function, with a self-funded employer or health insurance company actually responsible, at least in part, for the reimbursement. Each has an interest in claiming responsibility for the prescription. The classes as defined are likely to be rife with conflicts over who “paid” for each prescription.

In short, these classes should not be certified.

## 2. The Proposed Classes are Not Ascertainable

Moreover, the classes IBEW seeks to certify must meet the standard for ascertainability. “It is elementary that in order to maintain a class action, the class sought to be represented must be adequately defined and clearly ascertainable.” *DeBremaecker v. Short*, 433 F.2d 733, 734 (5th Cir. 1970); *see In re Sch. Asbestos Litig.*, 56 F.3d 515, 519 (3d Cir. 1995); *Chakejian v. Equifax Info. Servs.*, 256 F.R.D. 492, 497 (E.D. Pa. 2009) (stating a proposed class must be “adequately defined and clearly ascertainable”); 7A Wright & Miller, FEDERAL PRACTICE AND PROCEDURE, § 1760 (3d ed.) (The class description must be “sufficiently definite so that it is administratively feasible for the court to determine whether a particular individual is a member.”). A class may only be certified if “the class definition provides a court with tangible and practicable standards for determining who is and who is not a member of the class.” 5 JAMES WM. MOORE ET AL., MOORE’S FEDERAL PRACTICE § 23.21[1] (3d Ed. 2013).

Simply put, IBEW has failed to set forth *any* standards by which this court can determine membership in the classes, without requiring individualized analysis of each separate class member. Given the complex web of risk-sharing arrangements among insurers, PBMs, employers and other intermediaries, as well as the role of the federal and state governments in funding even “private” insurance (through, for example, Medicare Part D plans), it would be a complex and individualized task to identify which entities actually fit the class definition. Cremieux Decl. ¶ 60. To take just one example, PBMs generally administer pharmacy benefits for insurers, self-funded employers and others. PBMs usually deal directly with pharmacies, not the insurance provider (IBEW, for example, uses a PBM called SavRx). Thus PBMs, and not insurers, typically pay pharmacies for prescription drugs in the first instance. Sometimes the PBM is a mere pass-through, and the insurance company or self-funded employer is responsible

for the cost. Sometimes PBMs take on some level of risk for reimbursement costs. For example, PBMs may bear the risk of the “spread” between amounts they pay pharmacies for prescriptions and amounts insurers reimburse the PBMs. PBMs negotiate separate contracts with pharmacies and insurers, with separate reimbursement rates for various drugs. To the extent there was an “overcharge” here, PBMs therefore could have borne a portion as a result of the spread between their pharmacy and insurer reimbursement formulas.<sup>77</sup> In other instances, PBMs enter into “risk sharing or shared services agreements(s)” in which “the client and the PBM both assume some risk for the total cost of the prescription drug program.”<sup>78</sup> Such agreement may include guarantees on “per member annual drug spending” and “annual trending drug spending.” Insurers would bear part of the ultimate cost, but dividing responsibility would be complex.

The basic requirement of ascertainability is clearly missing with these proposed classes.

**G. IBEW’s Proposed Injunction Class Fails Because It Is Redundant of the Claims Asserted by Multiple Other Plaintiffs.**

Even if this Court determines that IBEW’s proposed injunction class meets the appropriate requirements of Rule 23(a) and Rule 23(b)(2), this Court “may nevertheless deny class certification” where “all the class members will benefit from an injunction issued on behalf of the named plaintiffs.” *Mills v. District of Columbia*, 266 F.R.D. 20, 22 (D.D.C. 2010); *see Blake v. Chemlawn Servs. Corp.*, 1988 WL 6151 at \*4–\*5 (E.D. Pa. Jan. 26, 1988). As this Court has stated, “an individual plaintiff can also obtain injunctive relief and, if this court renders a decision favorable to the individual plaintiffs, any relief will benefit automatically all potential class members. It will thus have the purpose and effect of a class action.” *Blake*, 1988 WL

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<sup>77</sup> Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies*, August 2005 at 9–10 (“FTC PBM Study”) (Ex. 28).

<sup>78</sup> Health Care Financing Administration Study of Pharmaceutical Benefit Management, undertaken by PriceWaterhouseCoopers LLP, June 2001 (“HCFA PBM Study”) at 91, 100 (Ex. 29).

6151, at \*5.

This is precisely the situation here. Multiple plaintiffs have moved this Court for injunctive relief. Any injunctive relief that could be granted by the Court would benefit the proposed members of the class. Thus, the class action device is not necessary for the federal injunction class.

### CONCLUSION

For the forgoing reasons, the Court should deny Indirect Purchaser Plaintiff's motion for class certification.

Dated: May 16, 2013

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**CERTIFICATE OF SERVICE**

I, Jack E. Pace III, hereby certify that on May 28, 2013, I caused true and correct copies of the redacted public version of Defendant Warner Chilcott's Opposition to Indirect Purchaser Plaintiffs' Motion for Class Certification to be served on the ECF system.

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